Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge <iad7@cdc.gov> Subject: FW: Advice on CDC Collaborating Center Date: 2020/09/03 11:59:46 Priority: Normal Type: Note From: Kerr, Lawrence (HHS/OS/OGA) Sent: Thursday, September 3, 2020 11:56 AM To: Martin, Rebecca (CDC/DDPHSIS/CGH/OD) <rtm4@cdc.gov>; Burr, Mara (HHS/OS/OGA) <Mara.Burr@hhs.gov>; Mciff, Colin (HHS/OS/OGA) <Colin.Mciff@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov> Cc: Richardson, Juliana (HHS/OS/OGA) < Juliana. Richardson@hhs.gov>; Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov> **Subject:** RE: Advice on CDC Collaborating Center (b)(5)What would be our next step? From: Martin, Rebecca (CDC/DDPHSIS/CGH/OD) < rtm4@cdc.gov> Sent: Thursday, September 3, 2020 11:51 AM To: Burr, Mara (HHS/OS/OGA) < Mara.Burr@hhs.gov >; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Mciff, Colin (HHS/OS/OGA) <Colin.Mciff@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov> Cc: Richardson, Juliana (HHS/OS/OGA) < Juliana. Richardson@hhs.gov>; Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov> Subject: RE: Advice on CDC Collaborating Center

From: Burr, Mara (HHS/OS/OGA) < Mara.Burr@hhs.gov>

Sent: Thursday, September 3, 2020 11:47 AM

Thank you for looping me in on this.

(b)(5)

To: Kerr, Lawrence (HHS/OS/OGA) < <u>Lawrence.Kerr@hhs.gov</u>>; Mciff, Colin (HHS/OS/OGA)

<Colin.Mciff@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>

Cc: Richardson, Juliana (HHS/OS/OGA) < <u>Juliana.Richardson@hhs.gov</u>>; Fernandez, Jose (OS/OGA)

<<u>Jose.Fernandez@hhs.gov</u>>; Martin, Rebecca (CDC/DDPHSIS/CGH/OD) <<u>rtm4@cdc.gov</u>>

Importance: High
Colin and Larry:
(b)(5)
Thanks.
Mara
Mara M. Burr, JD, LL.M Director, Multilateral Relations Office of the Secretary Office of Global Affairs U.S. Department of Health and Human Services Telephone: 202-205-4677 Mobile: (b)(6)
From: Kerr, Lawrence (HHS/OS/OGA) < Lawrence.Kerr@hhs.gov > Sent: Thursday, September 3, 2020 11:35 AM To: Mciff, Colin (HHS/OS/OGA) < Colin.Mciff@hhs.gov >; Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov >; Burr, Mara (HHS/OS/OGA) < Mara.Burr@hhs.gov > Cc: Richardson, Juliana (HHS/OS/OGA) < Juliana.Richardson@hhs.gov >; Fernandez, Jose (OS/OGA) < Jose.Fernandez@hhs.gov >; Martin, Rebecca (CDC/DDPHSIS/CGH/OD) < rtm4@cdc.gov > Subject: RE: Advice on CDC Collaborating Center
b)(5)

From: Mciff, Colin (HHS/OS/OGA) < Colin.Mciff@hhs.gov>

Subject: RE: Advice on CDC Collaborating Center

Sent: Thursday, September 3, 2020 11:30 AM To: Kerr, Lawrence (HHS/OS/OGA) < Lawrence.Kerr@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <<u>Garrett.Grigsby@hhs.gov</u>>; Burr, Mara (HHS/OS/OGA) <<u>Mara.Burr@hhs.gov</u>> Cc: Richardson, Juliana (HHS/OS/OGA) < Juliana.Richardson@hhs.gov >; Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov>; Martin, Rebecca (CDC/DDPHSIS/CGH/OD) < rtm4@cdc.gov> Subject: RE: Advice on CDC Collaborating Center (b)(5) Best, Colin From: Kerr, Lawrence (HHS/OS/OGA) < Lawrence.Kerr@hhs.gov> Sent: Thursday, September 3, 2020 11:27 AM To: Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov>; Mciff, Colin (HHS/OS/OGA) < Colin.Mciff@hhs.gov >; Burr, Mara (HHS/OS/OGA) < Mara.Burr@hhs.gov > Cc: Richardson, Juliana (HHS/OS/OGA) < <u>Juliana.Richardson@hhs.gov</u> >; Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov> Subject: Advice on CDC Collaborating Center Garrett, (b)(5)

Thank you,

Larry

Recipient: Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge <iad7@cdc.gov>

Sent Date: 2020/09/03 12:00:16 **Delivered Date:** 2020/09/03 11:59:46

Message Flags: Unsent

Boucher, David (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41293945651D475FA0413062A819AAC5-BOUCHER, DA <David.Boucher@hhs.gov>

Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>;

Zarrabian, Amanda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c650b07917242129deb0f942bb4cc10-Zarrabian, <amanda.zarrabian@hhs.gov>;

Ayala, Ana (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80a408be55b14221a42c2b91002d6bf7-Ayala, Ana <Ana.Ayala@hhs.gov>;

Biggins, Julia E CTR (USA) < julia.e.biggins.ctr@mail.mil>;

Birnkrant, Debra B (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57a9d96c3a884fc0808702ed5d3a7b4c-debra.birnk <Debra.Birnkrant@fda.hhs.gov>;

Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f16dc874b53240f7a323b1246027e71c-rosalind.ca <rdc6@cdc.gov>;

Chandrasekera, Ruvani (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=678d9ff8e02d477ab5d0516bd3659a34-Chandraseke <Ruvani.Chandrasekera@hhs.gov>;

Cho, David S (CBER) (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79853f418ac488c9cd10b70d1e2b0f1-david.cho.f <David.Cho@fda.hhs.gov>;

Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2063b181b77a49a4b498ee8b7afa7478-caitlin.cos <nrm9@cdc.gov>;

Wolfe, Daniel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01933911e406492fbd7f86e0235944d7-Wolfe, Daniel.Wolfe2@hhs.gov>;

Deussing, Eric (CDC/OD/OCS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e1290339b14ad6844f56b40d0c6661-eric.deussi <ncu0@cdc.gov>;

To: Diaz-Diaz, Carol (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b2b5f0685df417b9e2a0018c6fd251f-Diaz-Diaz, <Carol.Diaz-diaz@hhs.gov>;

Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>;

Higgs, Elizabeth (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e542539154ce59df4bedbc8741ebf-elizabeth.h <ehiqqs@niaid.nih.qov>;

Fitter, David L. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbd8cb8b5f054c98a5d907ce4a8f2bde-david.fitte <vid3@cdc.gov>;

Gentles, Andrew (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd01d5eb6d814cbcb9d6547155eb7596-andrew.gent <Andrew.Gentles@fda.hhs.gov>;

Poley, Gerald (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1652fb2d5ebc405db14139a73d364c23-gerald.pole <Gerald.Poley@fda.hhs.gov>;

Hassell, David (Chris) (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbfb0ff96e4119ac7a3b3abaf71a3d-Hassell, Da <David.Hassell@hhs.gov>;

Schiltz, Helen (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f2008d8dd04f5ea7695f37929f6df7-helen.schil <hschiltz@niaid.nih.gov>;

Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.marshilary.marston@nih.gov>;

Hughes, Craig (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4ade4d09cb444bb995d03c84d1f0746-Hughes, Cra<Craig.Hughes@hhs.gov>;

Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge

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<iad7@cdc.gov>;
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Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>;

Walldorf, Jenny A. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2813aaef1f94f96bb247826243e3811-jenny.walld <igf4@cdc.gov>;

Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff8628c4e15948b3b03805d50c3d0eee-Kahn, Emily <ebk9@cdc.gov>;

Bok, Karin (NIH/VRC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d1dc469e6684003a0a89b132e8b7916-karin.bok.n <karin.bok@nih.gov>;

Kayvon Modjarrad <kmodjarrad@hivresearch.org>;

Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) < jennifer.m.kishimori.mil@mail.mil>;

Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre <Lawrence.Kerr@hhs.gov>;

Ledgerwood, Julie (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45778324d47644eeb9fced6acbf5108f-julie.marti <jumartin@niaid.nih.gov>;

Madock, Christa M CIV USARMY MEDCOM USAMMDA (US) <christa.m.madock.civ@mail.mil>; Marinissen, Maria (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d42fb4d94b041ee88e4f7dd5743e893-Marinissen, <Maria.Marinissen@hhs.gov>;

Gruber, Marion (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a0d24180354f55a133fec3ade6c972-marion.grub <Marion.Gruber@fda.hhs.gov>;

Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks kepter.Marks@fda.hhs.gov;

Meltzer, Martin I. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d4e5aa77412403b9ae866e4c8312e79-Meltzer, Ma <qzm4@cdc.qov>;

Choi, Mary Joung (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f8d54090194cf7be8e49b80bca7328-mary.choi.c <whz2@cdc.gov>;

Merchlinsky, Michael (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a4736917274e3783b5570c29518cdf-Merchlinsky <Michael.Merchlinsky@hhs.gov>;

Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>;

Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62643d5586b14f1798171ce903c12ea4-Montgomery, <ztq9@cdc.gov>;

Moudy, Robin (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d421d3e0f6474bc3857583cfc5870d69-Moudy, Robi <Robin.Moudy@hhs.gov>;

Nelson Michael <nmichael@hivresearch.org>;

Bryant, Paula (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4fe56a126fc4da2a4a187dece3928e2-paula.bryan

Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US) (nathan.j.pawlicki.ctr@mail.mil) <nathan.j.pawlicki.ctr@mail.mil>;

Krause, Philip (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db30c21c61424ee0b278cee85f9a71f1-philip.krau <Philip.Krause@fda.hhs.gov>;

Arthur, Ray (CDC/DDPHSIS/CGH/DGHP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=855f8ca30adc4a59906fd6647ac8371d-Arthur, Ray <rca8@cdc.gov>;

Helfand, Rita (CDC/DDID/NCEZID/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28a17ce03de24abbb3e9c9e1363c4017-Helfand, Ri <rzh7@cdc.gov>;

Sabourin, Carol (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46ae47e8f4b34a6e9d2804b44e192651-Sabourin, C <Carol.Sabourin@hhs.gov>;

Samuel, Anita (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9238fa3a950b4c118cad476c0ef01c40-anita.samue <kyp8@cdc.gov>;

Simon, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7d46815edf04bb28ac3ea25ff3d3268-Simon, Davi <David.Simon@hhs.gov>;

Styrt, Barbara (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd3d53d2e3994f678050e141d6a0b9db-barbara.sty <Barbara.Styrt@fda.hhs.gov>;

Suzanne Mate <suzanne.e.mate.mil@mail.mil>;

Taylor, Kimberly (NIH/NIAID) [E] <kimberly.taylor3@nih.gov>;

Taylor, Marva (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34ad843b32e14d9fb5e825646336d169-Taylor, Mar <Marva.Taylor@hhs.gov>;

Hyde, Terri (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=653839b51d4442a7b5ad95e605761104-Hyde, Terri <tkh4@cdc.gov>;

Thompson, Elizabeth (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebdef60dc3794a8db0daf295649d05f0-elizabeth.t <Elizabeth.Thompson@fda.hhs.gov>;

Turley, Danielle (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=befe52d068424520bd5f5eddb942ff4d-Turley, Dan <Danielle.Turley@hhs.gov>;

Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>;

Weinberger, Collin (OS/OGA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641554fc7843407585827af5898d9c26-Weinberger, <Collin.Weinberger@hhs.gov>;

Yu, Yon C. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbdd97c36ce040d8adc6dc54932741bd-Yu, Yon C. <fkb8@cdc.gov>;

Murray, Jeffrey S (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85e81cda2e9b4c3f943c5b1ecdd82b01-jeffrey.mur <Jeffrey.Murray@fda.hhs.gov>;

Tsai, Chia-Wei CTR USARMY MEDCOM USAMMDA (USA) (chia-wei.tsai.ctr@mail.mil) <chia-wei.tsai.ctr@mail.mil>;

Redd, John (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ba3fed4ee8646ec849a5a87136a24f6-Redd, John <John.Redd@hhs.gov>

CC: Kayvon Modjarrad < kmodjarrad@eidresearch.org>

Subject: Ebola MCM Scientific Working Group

Date: 2019/10/29 11:36:38 **Start Date:** 2019/11/05 10:30:00

End Date: 2019/11/05 12:00:00
Priority: Normal

Type: Appointment

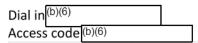
Location: Teleconference

Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov); Ayala, Ana (OS/ASPR/SPPR); Biggins, Julia E CTR (USA); Birnkrant, Debra B (FDA/CDER); Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov); Chandrasekera, Ruvani (OS/ASPR/SPPR); Cho, David S (CBER) (FDA/CBER); Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP); Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov); Deussing, Eric (CDC/OD/OCS); Diaz-Diaz, Carol (OS/ASPR/BARDA); Disbrow,

Attendees: Gary (OS/ASPR/BARDA); Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov); Fitter, David L. (CDC/DDPHSIS/CGH/GID); Gentles, Andrew (FDA/CDER); Gerald Poley (FDA/CDER) (Gerald.Poley@fda.hhs.gov); Hassell, David (Chris) (OS/ASPR/IO); Helen Schiltz (helen.schiltz@nih.gov); Hilary (NIH/NIAID) Marston [E] (hilary.marston@nih.gov); Hughes, Craig (OS/ASPR/BARDA); Inger K. Damon (CDC/DDID/NCEZID/DHCPP) (iad7@cdc.gov); Inger-Marie Vilcins (ivilcins@hivresearch.org); Jenny A. Walldorf (CDC/DDPHSIS/CGH/GID) (igf4@cdc.gov); Kahn, Emily B.

(CDC/DDID/NCEZID/DPEI); Karin (NIH/VRC) Bok [E] (karin.bok@nih.gov); Kayvon Modjarrad; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil); Lawrence Kerr (HHS/OS/OGA) (Lawrence.Kerr@hhs.gov); Ledgerwood, Julie (NIH/NIAID) [E]; Madock, Christa M CIV USARMY MEDCOM USAMMDA (US); Marinissen, Maria (HHS/OS/OGA); Marion Gruber (FDA/CBER) (Marion.Gruber@fda.hhs.gov); Marks, Peter (FDA/CBER); Martin I. Meltzer (CDC/DDID/NCEZID/DPEI) (qzm4@cdc.gov); Mary Joung Choi (CDC/DDID/NCEZID/DHCPP) (whz2@cdc.gov); Merchlinsky, Michael (OS/ASPR/BARDA); Michael Mair (FDA/OC) (Michael.Mair@fda.hhs.gov); Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP); Moudy, Robin (OS/ASPR/SPPR); Nelson Michael; Paula (NIH/NIAID) Bryant [E] (paula.bryant@nih.gov); Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US) (nathan j.pawlicki.ctr@mail.mil); Philip Krause (FDA/CBER) (Philip.Krause@fda.hhs.gov); Ray Arthur (CDC/DDPHSIS/CGH/DGHP) (rca8@cdc.gov); Rita Helfand (CDC/DDID/NCEZID/OD) (rzh7@cdc.gov); Sabourin, Carol (OS/ASPR/BARDA); Samuel, Anita (CDC/DDPHSIS/CGH/GID); Simon, David (OS/ASPR/BARDA); Styrt, Barbara (FDA/CDER); Suzanne Mate; Taylor, Kimberly (NIH/NIAID) [E]; Taylor, Marva (OS/ASPR/BARDA); Terri Hyde (CDC/DDPHSIS/CGH/GID) (tkh4@cdc.gov); Thompson, Elizabeth (FDA/CDER); Turley, Danielle (OS/ASPR/BARDA); Walke, Henry (CDC/DDID/NCEZID/DPEI); Walker, Robert (OS/ASPR/BARDA); Weinberger, Collin (OS/OGA) (CTR); Yu, Yon C. (CDC/DDID/NCEZID/DPEI); Murray, Jeffrey S; Tsai, Chia-Wei CTR USARMY MEDCOM USAMMDA (USA) (chia-wei.tsai.ctr@mail.mil); Redd, John (OS/ASPR/SPPR); Kayvon Modjarrad

This is an off-week meeting to discuss a potential USG recommendation for geographic vaccination in DRC.



Boucher, David (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP Sender: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41293945651D475FA0413062A819AAC5-BOUCHER, DA <David.Boucher@hhs.gov>

Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>;

Zarrabian, Amanda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c650b07917242129deb0f942bb4cc10-Zarrabian, <amanda.zarrabian@hhs.gov>;

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Sent Date: 2019/10/29 11:36:38

ESTIMATING THE NUMBER OF EBOLA CASES AND PROPORTION OF CASES IN EFFECTIVE ISOLATION, THE DEMOCRATIC REPUBLIC OF CONGO, 2018-2019

Ebola Case Projection Memo V3.20

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Background: On 1 August 2018, the Ministry of Health of the DRC declared a new outbreak of Ebola. As of 22 October 2019, 3,243 Ebola probable and confirmed cases have been reported by the WHO¹, of whom 2,169 (67%) have died. To prevent onward transmission and perpetuation of the outbreak, it is critical to identify cases early so that they may be effectively isolated², either by placement in an Ebola Treatment Unit and/or through effective vaccination of their contacts and contacts-of-contacts, to prevent onward transmission. Additionally, early treatment likely increases the chance of survival.

Questions/Objectives:

- a. What is the effectiveness of current intervention efforts, measured as the proportion of identified cases that are currently being identified and effectively isolated, either by placement in an Ebola Treatment Unit and/or by effective vaccination of their contacts and contacts-of-contacts, to prevent onward transmission?
- b. What is the potential impact of a hypothetical increase in cases effectively isolated on the likelihood of onward transmission?

Date: 23 October 2019

Authors: Centers for Disease Control and Prevention (CDC): Bishwa Adhikari, Brad Greening, Evin Jacobson, Seonghye Jeon, Emily Kahn, Gloria Kang, Martin Meltzer, Health Economics and Modeling Unit (HEMU/DPEI); James Fuller (CGH/DGHP)

¹ WHO Ebola Health update – DRC 2019 – Ebola daily case numbers – 22 October 2019 (https://www.who.int/emergencies/diseases/ebola/drc-2019/)

² Effective isolation means preventing onward transmission of Ebola by ensuring that a patient is either physically isolated and / or their contacts are protected from infection. In addition, effective isolation can include minimizing the number of treatment facilities per case; vaccination of health care workers, frontline workers and community members, as well as Safe and Dignified Burials when needed.

RED FLAG ALERT: Based on the most recent data provided, we currently estimate that 65% of cases are effectively isolated, the same as estimated in the previous memo (9 October 2019). Assuming no changes, the epidemic is now projected to end by 5 May 2020 with 3,410 total cases. Other outbreak indicators (Table 2) have remained constant or shown sight signs of worsening, indicating that the situation has not notably changed over the last four weeks. Given the unknown degree of under-reporting of cases, any estimates of improvements should be interpreted with caution. To bring a rapid end to the outbreak, the proportion of cases in effective isolation (ideally within 3 days of symptom onset) will need to reach (and be sustained at) approximately 70%.

BOTTOM LINE SUMMARY/SUMMARY OF RESULTS

BASE ANALYSIS

- Percent not effectively isolated: Based on 3,250 total cases reported as of 22 October 2019, approximately 35% of cases are not being effectively identified and isolated (i.e., 65% are effectively isolated) to prevent transmission of illness to others (see Table 1).
- Projected number of cases: Assuming that the proportion of Ebola cases not effectively isolated <u>remains</u> unchanged at 35% (Table 1), there will be an estimated cumulative total of 3,409 reported cases by 23 April 2020 (Figure 1a).
- Projections indicate that if the proportion of cases not effectively isolated remains at 35% (i.e., 65% effectively isolated), the number of new cases each week will decline slowly from now (early October 2019) through the end of April 2020, at which time there will be approximately 1 new case each week (Figure 1b). Assuming no changes, the epidemic would then end by 5 May 2020 with 3,410 total cases.

SENSITIVITY ANALYSIS

- The projected number of future cases is sensitive to the proportion of cases that are effectively isolated.
 - If the proportion of cases that are being effectively isolated is decreased from 65% to 55% (i.e., 45% not effectively isolated), by 23 April 2020 there will be an estimated cumulative total of 3,653 Ebola cases, with 7 new cases per week (Figure 1b). In this scenario, the outbreak continues beyond September 2020.
 - If the proportion of cases that are effectively isolated is raised from 65% to 75% (i.e., 25% not effectively isolated), the outbreak effectively ends by 4 February 2020 with a total of 3,329 total cases.
- Illustration: If the proportion of cases effectively isolated gradually improves: An illustration of the potential impact of improved effectiveness of interventions was constructed by assuming the following: The proportion of Ebola cases effectively isolated is set at 65% (i.e., 35% not effectively isolated, Table 1) through 26 September 2019 and remains at 65% effectively isolated (35% not) during 27 September 26 October 2019. Then, 70% of cases are effectively isolated (30% not) from 27 October 25 December 2019; and 95% of cases are effectively isolated (5% not) from 26 December 2019 onward. Under those assumptions, the outbreak will end by 18 January 2020 (i.e., isolation of last case) with an estimated cumulative case count of 3,376 cases (Figure 1a).

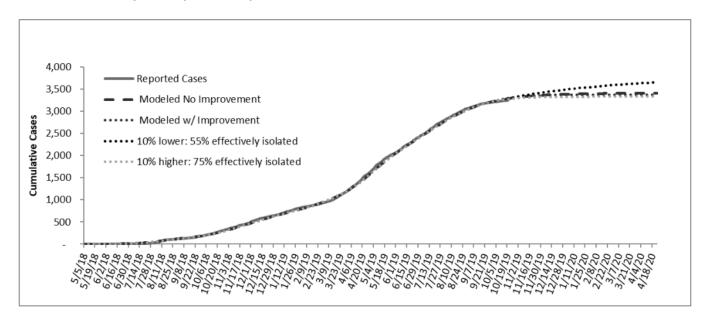
MAIN TABLES AND FIGURES

Table 1. The estimated proportion of Ebola cases that are not effectively isolated, January 2019 - present^{1†}

Outbreak Days	Dates	Proportion of cases <u>not</u> effectively isolated
241-270	31 Dec 2018 – 29 Jan 2019	50%
271-300	30 Jan – 28 Feb 2019	62%
301-330	1 Mar – 30 Mar 2019	67%
331-360	31 Mar – 29 Apr 2019	60%
361-390	30 Apr – 29 May 2019	43%
391-420	30 May – 28 June 2019	50%
421-450	29 June – 28 July 2019	48%
451-480	29 July – 27 Aug 2019	41%
481-510	28 Aug – 26 Sep 2019	35%
Estin	nating cases forward assuming NO	Change in percent cases <u>not</u> effectively isolated
511-720 [*]	27 Sep 2019 – 23 Apr 2020	35%
Estin	nating cases forward assuming DE	CREASES in percent cases <u>not</u> effectively isolated
511-540	27 Sep – 26 Oct 2019	35%
541-570	27 Oct – 25 Nov 2019	30%
571-600	26 Nov – 25 Dec 2019	30%
601-720	26 Dec 2019 – 23 Apr 2020	5%

These estimates were produced by fitting modeled data to reported case counts as described in methods below and in Appendix 1.

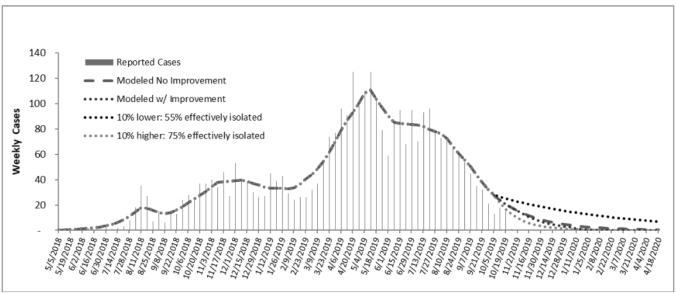
Figure 1a. Projected <u>cumulative</u> number of Ebola cases through 18 April 2020, with* and without** improvements in the proportion of cases effectively isolated (based on case reports as of 22 October 2019), base and sensitivity*** analysis – all reported cases¹



[†]The proportion of cases not effectively isolated for earlier time periods are listed in Appendix Table A4.1.

^{*}This assumes that no changes in the proportion of Ebola cases effectively isolated occurs after the date through which data have been provided.

Figure 1b. Projected <u>weekly</u> number of Ebola cases through 18 April 2020, with* and without** improvements in the proportion of cases effectively isolated (based on case reports as of 22 October 2019), base and sensitivity*** analysis – all reported cases[¶]



*The estimates of the scenario "Modeled with Improvement" were calculated assuming that there will be incremental improvements in effective isolation such that: 65% of cases are effectively isolated from 28 August – 26 October 2019; 70% of cases are effectively isolated from 27 October – 25 December 2019; and 95% of cases are effectively isolated from 26 December 2019 onward (see Table 1).

¶For some cases, we imputed date of symptom onset. See Methods section for details.

IMPORTANT CAVEATS

All case estimates and projections presented are based on reported case data provided by WHO on 22 October 2019, unless otherwise stated.

- a) The accuracy of case estimates and projections depends on the accuracy of case reports.
- The estimates and projections may change as more data are reported.
- c) Projections made for future dates become more uncertain the farther out we project, as it is unknown how conditions may change over time. The projections provided assume that the present trends and conditions remain unchanged into the future and should be interpreted as providing relative comparisons between intervention strategies (given all caveats and assumptions listed). The estimates should not be considered exact predictions of the future.

EXPANDED RESULTS

Other epidemiologic indicators (Table 2) help evaluate the estimates presented here and assess the overall success of current response efforts. For example, during the past 3 weeks (from 2 October to 22 October), 22% of all new Ebola cases were only identified as Ebola cases at or after the time of death (i.e., community deaths), and 52% of new cases were not previously identified as contacts of other cases. Furthermore, only 33% of new cases were isolated early in the course of disease, i.e., within 3 days of symptom onset.

^{**}The estimates of future cases were produced by assuming that 35% of identified cases are only being isolated after they have infected other people and caused onward transmission (Table 1).

^{***}Sensitivity analyses demonstrate the projected number of Ebola cases if the modeled estimate of cases effectively isolated is +/ - 10% than the base analysis (Table 1) beginning 27 September 2019.

Table 2: Additional outbreak indicators: Characteristics of new confirmed cases (n=59) for 18 September – 08 October 2019

Characteristic	Cases	%	Target %*
Community Deaths [†]	11	22%	0%
Not Known Contacts	26	52%	20%
Cases isolated within 3 days of symptom onset	16	33%	70%
Known and Monitored Contacts	21	42%	80%
Health Care Worker Infections	1	2%	0%

*Cases identified at time of death. The high proportion of community deaths reported among confirmed cases, persistent delays in detection and isolation in ETUs, and challenges in the timely reporting and response to probable cases all collectively increase the likelihood of further chains of transmission in affected communities and contribute to increased risk of geographical spread within the Democratic Republic of the Congo and to neighboring countries. (CDC/CGH/DGHP Communication, 14 August 2019)

*Targets are based on the assumption that in order to rapidly end the outbreak approximately 70% of cases must be effectively isolated. (1) This was shown to be a realistic policy goal in the 2014-16 West African Ebola outbreak. (12)

ACCURACY

To track the accuracy of model estimates, we have been comparing the projected cases counts to the reported cases counts for 14 days, 28 days and 42 days from the date of the initial model run (Appendix Table A2.1). Since 30 January 2019, when we began imputing dates of symptom onset, modeled projections have been accurate to approximately 5% for the 14-day projections and around 10% for the 28-day projections on average (Appendix Table A2.1). Most projections have been under-estimated (i.e., actual cases recorded at a future date have been greater than those estimated from the model when the memo was produced). Some memos, however, included over-estimates of future cases (i.e., model results were greater than the resulting number of actual cases) (Appendix Figure A2.1); this may be due to an approximate 25% of cases not being reported during late May – early June 2019 (10,11). Since memo version 3.10 (produced 5 June 2019), model accuracy has notably improved, with projected estimates falling within 10% of actual case counts as far out as 12 weeks into the future. (Appendix: Table A2.1, Figure A2.1).

SENSITIVITY ANALYSIS

We conducted a sensitivity analysis to show the impact of ±10% difference in the percentage of cases that are effectively isolated on projections of future case counts (Figures 1a and 1b). In the base analysis, we estimate that 65% of cases are being effectively isolated from 28 August 2019 onward, resulting in an estimated 3,409 Ebola cases by 23 April 2020. If the estimated proportion of cases that are effectively isolated is lowered to 55% beginning 27 September 2019, there would be an estimated 3,653 Ebola cases by 23 April 2020 with 7 new cases per week; in this scenario, the outbreak would be expected to continue beyond September 2020. If the estimated proportion of cases that are effectively isolated is raised to 75% beginning 27 September 2019, the outbreak would be expected to effectively end as of 4 February 2020 with a total of 3,329 cases.

METHODS

We used the EbolaResponse model (available at http://dx.doi.org/10.15620/cdc.24900) to determine the proportion of Ebola cases in two categories:

- Patients effectively isolated (i.e., either by placement in an Ebola Treatment Unit and/ or their contacts and contacts-of-contacts are effectively vaccinated, to prevent onward transmission), such that there is a reduced risk of disease transmission
- 2. Patients not effectively isolated, such that there is continued risk of onward transmission.

Estimates of the proportions of cases in these categories were produced by fitting the modeled data to the actual confirmed/probable cumulative case counts from DRC (Appendix 1: Figure A1.2) provided by the Goma Analytic Cell, which reports to the DRC Ministry of Health's Emergency Operations Center.

Imputation of date of symptom onset for cases missing data

Cases without reported date of symptom onset were assigned a date of symptom onset that was 7 days earlier than their case report dates. Of the 3,250 cases (3,133 confirmed + 117 probable) included in the analyses reported in this memo, 183 (6%) cases were missing date of symptom onset; for these cases we used the imputed date of symptom onset.

Additional description of Methods:

A detailed description of the methods and assumptions used in the EbolaResponse model is provided in Appendix 1.

LIMITATIONS

- The modeled data presented here project case counts through 23 April2020. Estimates of future cases <u>become</u> more uncertain the farther out we project, as it is unknown how conditions may change over time. The projections provided assume that the present trends and conditions remain unchanged into the future and should be interpreted as providing the estimated impact of intervention vs. no intervention strategies.
- The EbolaResponse model uses 30-day increments to model changes in the proportion of Ebola cases assigned to each category.
- The main set of results presented in this memo do not take into account any corrections for underreporting. The World Health Organization has estimated that up to 25% of cases may not be recorded/reported (10, 11). There are no data on how such underreporting may have changed over the course of the epidemic to date.

APPENDIX 1: EbolaResponse tool: Methods and Assumptions

Model overview:

We built a spreadsheet-based model, called EbolaResponse, that allows a user to estimate the number of Ebola cases in the DRC and the proportion of cases that are effectively isolated such that onward Ebola transmission is prevented (1).

Type of model:

Our model, EbolaResponse, tracks patients through the following states: Susceptible (not yet infected); infected people incubating Ebola virus (but not yet infectious), infectious, recovered or dead (an SIIR model). The model is in effect, a Markov Chain model, and is similar in concept to that built by Chowell et al. (2). The one exception is that Chowell et al. included a state labeled "Exposure" and did not include our "incubating but not infectious category".

We use probabilities, drawn from reports of Ebola outbreaks, to model the daily movement of patients between and within the states. For example, for duration of incubation period, we adapted data from (3), which indicates the probability (likelihood) that patients will incubate 1, 2, 3 or more days, up to a maximum of 25 days (see below).

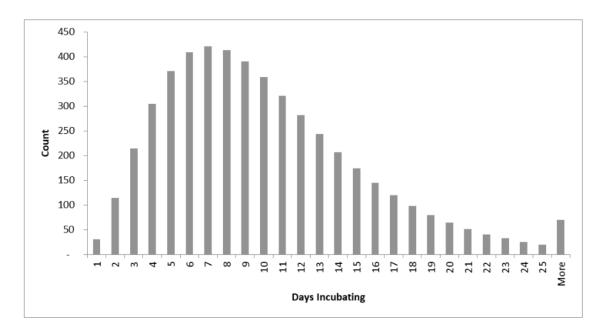
Progression only: A patient can only progress forward through the model, and can never regress (e.g., can never go from incubating back to susceptible). Nor can a patient skip a state (e.g., go from incubating to recovered, skipping infectious).

Community size: We used a community size of 78.7 million people (the estimated 2016 national population of the DRC, (3). The community size can be readily altered in the model.

Incubation period: We adapted published *probability distribution* data (3) to construct a gamma probability distribution of incubating with Ebola (Figure A1.1 and Table A1.1). We use a mean incubation period of 10.02 days (3).

Previous data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda (2), estimated mean incubation periods of 5.30 (SD 0.23) and 3.35 (SD 0.49) days, respectively. These appear to be lower than other published estimates (5, 6). Some of the differences may be attributable to different sub-types of the virus (5). Within the EbolaResponse model, the probability distribution for incubation can be readily changed to almost any structure desired, with an upper limit of 25 days incubation.

Figure A1.1. Frequency distribution of probability of incubating with Ebola for a population = 5,000*



^{*} Source: Adapted from (3).

Table A1.1: Frequency distribution of probability of incubating with Ebola

Days	Frequency	Percent	Cumulative Percent	Days	Frequency	Percent	Cumulative Percent
1	31	0.6%	0.2%	14	207	4.1%	79.6%
2	114	2.3%	1.6%	15	174	3.5%	83.4%
3	215	4.3%	4.9%	16	145	2.9%	86.6%
4	305	6.1%	10.1%	17	120	2.4%	89.2%
5	371	7.4%	16.9%	18	98	2.0%	91.4%
6	409	8.2%	24.7%	19	79	1.6%	93.2%
7	421	8.4%	33.1%	20	64	1.3%	94.6%
8	413	8.3%	41.5%	21	51	1.0%	95.7%
9	391	7.8%	49.5%	22	60	1.2%	96.7%
10	358	7.2%	57.0%	23	50	1.0%	97.4%
11	321	6.4%	63.8%	24	45	0.9%	98.0%
12	282	5.6%	69.8%	25	35	0.7%	98.4%
13	243	4.9%	75.1%				
				Totals	5,000	100.0%	

Source: Adapted from (3).

Infectious period:

Based on WHO data, we used an infectious period of 6 days (3). This would include any time taken for a traditional burial. Chowell et al, using data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda, estimated mean infectious periods of 5.6 and 3.35 days, respectively (2). This period of 6 days includes all stages of symptomatic illness. It is true that patients may be symptomatic for longer periods (see 3) but being symptomatic is different than having the risk of onward transmission.

Note that the risk of onward transmission, absent effective isolation, does change as a patient becomes sicker (7, 8). However, EbolaResponse does not track individual patients. Instead, the model employs aggregate (e.g., mean) risk of onward transmission, aggregated over the entire period of symptomatic illness (1).

Potential risk: The following description from northern Uganda indicates the potential risk, due to possible contact with a victim's body fluids, posed by traditional burial of an Ebola victim: "A brief study indicated that once a person died, his or her paternal aunt (father's sister) was called to wash and prepare the body for burial. If the father did not have a sister, an older woman in the victim's patriline was asked to prepare the body. Generally, the woman removed the clothes from the body, washed the body, and dressed the deceased in a favorite outfit. At the funeral, all family members ritually washed their hands in a common bowl, and during open casket all were welcome to come up to deceased person and give a final touch on the face or elsewhere (called a love touch). The body was then wrapped in a white cloth or sheet and buried." (9)

Population "governor"

Although we explicitly don't include an "exposed" population element in the model, we do include a population "governor" that prevents the model from calculating more cases than the inputted population. This "over-calculation" could happen if one assumes that there is a relatively large percentage (defined below) of the population that become infected and are not effectively isolated, presenting a risk of onward disease transmission (Table A1.3).

We programmed the governor by simply reducing the daily estimate of the persons newly infected proportionate to the cumulative reduction in the susceptible population, as follows:

Factor to reduce estimate of newly infected at Day t = (Model population – cumulative total of newly infected up to day (t-1)/ model population.

What this "governor" essentially does is to reduce, on a daily basis, the effective number of persons infected (i.e., effectively lowers the risk of transmission inputs shown in Table A1.3). In most instances, with "large populations," this

governor is unlikely to impact the calculations. The "governor" only begins to appreciably impact estimates (i.e., reduce them) when approximately 40% - 50% of the population have become infected.

Population and numbers initially infected
Country: The Democratic Republic of the Congo

Total Population: 78.7 million Number Initially Infected: 1

Distribution of patient by category over time

As explained in the main text, we split the patients into two categories of isolation, as follows:

- 1. Patients effectively isolated (i.e., hospitalized in ETCs or otherwise receiving medical care), such that there was reduced contact with others and a reduced risk of disease transmission.
- 2. Patients not effectively isolated, such that there was continued risk of onward transmission.

We explain how we calculate the percentage of patients in each category in the "goodness-of-fit" sub-section (below).

The risk of onward transmission from an Ebola patient to susceptible persons, by patient category, is shown in Table A1.3.

The distribution of patients into these categories affects the overall progress of the epidemic. The more patients in the "effectively isolated" category, the slower the progress of the epidemic because this category has a transmission rate of less than 1 person infected per infectious person. The distribution of patients into these categories, and how we changed those distributions over time, is shown in Table 1.

Table A1.3: Risk of onward transmission by category of patient: Values fitted to data compared to those in the literature

Patient category		Daily risk of onward tra	nsmission	Total numbers infected per infectious person**			
	Values fro	om literature (95% CI)†	Values used to fit	Value	Values from		
			to data in DRC*	literatur	e (95% CI)	estimates	
Effectively	DRC	0.1134	0.03	DRC	0.4	0.18	
isolated		(0.00001 - 0.5842)			(0 - 2.2)	_	
	Uganda	0.0017	•	Uganda	0.01	-	
		(0.0 - 0.918)			(0 - 3.5)		
No effective	DRC	1.0932	0.3	DRC	1.8	1.8	
isolation		(0.00001 - 1.4281)			(0 - 2.3)	_	
	Uganda	0.066		Uganda	0.1		
		(0.0 - 3.0367)			(0 - 3.2)		

^{*} These are the values used in the model in order to obtain a "good fit" to the data-to-date.

Source; Adapted from Legrand et al., 2007 (6).

Goodness-of-Fit:

Scenarios: Fitting to the existing data

For the original conception of the model, we essentially "reverse engineered" the following variables:

- i) Percentage of patients in each of the categories (effectively isolated; No effective isolation), with percentages changing over time (increments of 30 days) (see Main Text, Table 1).
- ii) Risk of transmission by type of patient, with daily risk of onward transmission changing over time (increments of 30 days) (see Appendix Table A1.3).

^{**} Values of "Total number of persons infected per infectious person": When these values remain below 1 person infected per infectious person, then the epidemic will eventually end. For model: These are the equivalent values used to fit the model to the data, assuming 6 days of infectiousness (e.g., $0.3 \times 6 = 1.8$ persons infected per infectious person as per model fit)

[†] Values adapted from weekly values given by Legrand et al (6), from Ebola outbreaks in 1995 in Democratic Republic of Congo (DRC) (formerly Zaire), 2000 in Uganda. CI = Confidences Intervals.

^{††} We used, as proxies for "effective isolation," Legrand et al.'s measurements of "community component" (without burial) from DRC, as these were below 1.

For the purpose of this analysis, we held fixed the previously used values for risk of transmission and only varied the percentage of patients in each of the three categories. Essentially, we "balance" the percentages in "effectively isolated" and "NOT effectively isolated" until the plot of the model "fits" the plot of the actual data, as shown in Figure A1.2. Figure A1.2 shows the goodness-of-fit, comparing estimates of cases produced using EbolaResponse model to reported confirmed and probable Ebola cases.

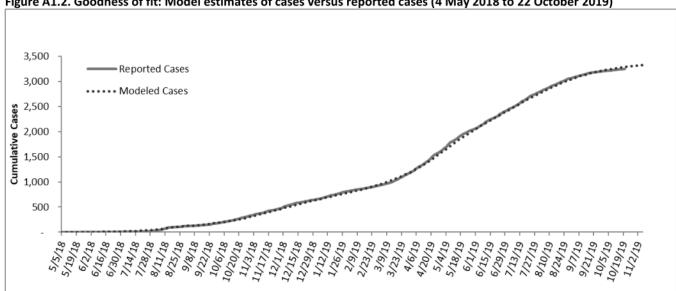
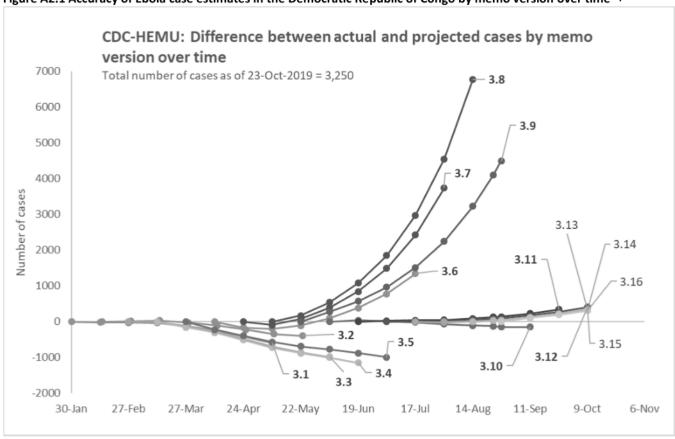


Figure A1.2. Goodness of fit: Model estimates of cases versus reported cases (4 May 2018 to 22 October 2019)

APPENDIX 2: Accuracy of Model Estimates

Figure A2.1 Accuracy of Ebola case estimates in the Democratic Republic of Congo by memo version over time*†



^{*}Note: See Table A2.1 for detailed summary of accuracy for all memos produced.

[†] The graph shows plots of accuracy, in 2-week segments, of selected memo versions of previous memos indicated by the version number. The y-axis represents count differences between modeled future cases and actual case counts on a given date. For example, the plot of memo version 3.7 (produced 24 April 2019), shows that those estimates of cases expected by 8 May 2019 differed by about 88 cases (5%) below the actual number of cases that occurred on that date. By 19 June 2019, the estimates produced on 24 April 2019 were approximately 37% greater (N = 847 cases) than actually reported. This decrease in accuracy is attributed to the temporary decline in reported cases in late May – which may be due to an approximate 25% of cases not being reported during that period. (10, 11)

Figure A2.2 Boxplot of accuracy of Ebola case estimates in the Democratic Republic of Congo

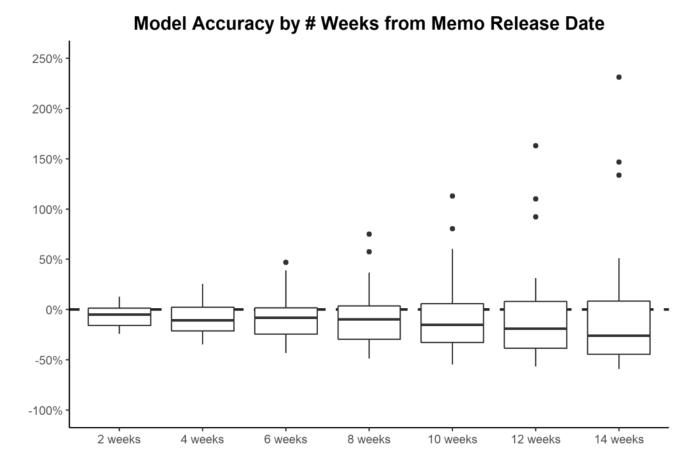


Figure A2.2 is a box-plot of accuracy of all the results reported in the memos (Figure A2.1), regardless of the date of when the estimate was made. The plot is given in standard Tukey format, where the boxes plot the range of the middle 50% of all estimates (Quartile 1 – Quartile 3). The box is split by a line indicating the median. The 'whiskers' extend to the farthest point that are not considered outliers, where an outlier is shown by a dot, and is defined as being >1.5x the interquartile range (Quartile 1 – Quartile 3) from the end of the box.

Interpretation: The majority of the memos have under-estimated reported cases by less than 50% (i.e., the boxes are between 0% and -50%). A small percentage (less than 10%) of estimates over-estimated by more than 100% (the top of the "whiskers' at 10, 12 and 14 weeks), however, all such estimates are considered outliers according to the definition given above.

Table A2.1. Accuracy of Ebola case estimates in Democratic Republic of Congo, 2-, 4-, and 6-weeks post-estimate*^

				14-day (2 weeks)			28-day (4 weeks)			42-day (6 weeks)					
Memo \	ersion and	Data date ar	nd total		(Cases			Cases				Cases		
	Date	reported	cases	Date	Actual	Estimated	% diff	Date	Actual	Estimated	% diff	Date	Actual	Estimated	% diff
1.1	11-Oct-18	5-Oct-18	179	19-Oct-18	260	199	-23%	2-Nov-18	330	216	-35%	16-Nov-18	410	232	-43%
2.0	18-Oct-18	16-Oct-18	214	30-Oct-18	317	240	-24%	13-Nov-18	386	268	-31%	27-Nov-18	462	297	-36%
2.1	23-Oct-18	23-Oct-18	238	6-Nov-18	347	289	-17%	20-Nov-18	424	329	-22%	4-Dec-18	504	368	-27%
2.2	6-Nov-18	5-Nov-18	305	19-Nov-18	422	352	-17%	3-Dec-18	500	398	-20%	17-Dec-18	580	443	-24%
2.3	14-Nov-18	14-Nov-18	339	28-Nov-18	467	411	-12%	12-Dec-18	554	475	-14%	26-Dec-18	618	544	-12%
2.4	21-Nov-18	21-Nov-18	373	5-Dec-18	513	442	-14%	19-Dec-18	589	509	-14%	2-Jan-19	<i>650</i>	580	-11%
2.5	6-Dec-18	4-Dec-18	458	20-Dec-18	596	504	-15%	3-Jan-19	653	550	-16%	17-Jan-19	723	591	-18%
2.6	19-Dec-18	17-Dec-18	542	2-Jan-19	<i>650</i>	<i>570</i>	-12%	16-Jan-19	721	623	-14%	30-Jan-19	799	674	-16%
2.7	2-Jan-19	2-Jan-19	598	16-Jan-19	721	593	-18%	30-Jan-19	799	623	-22%	13-Feb-19	859	648	-25%
2.8	15-Jan-19	15-Jan-19	648	29-Jan-19	797	630	-21%	12-Feb-19	857	658	-23%	26-Feb-19	914	681	-25%
V 3.1	30-Jan-19	30-Jan-19	733	13-Feb-19	859	837	-3%	27-Feb-19	924	900	-3%	13-Mar-19	997	962	-4%
V 3.2	14-Feb-19	14-Feb-19	820	28-Feb-19	931	948	2 %	14-Mar-19	1006	1037	3%	28-Mar-19	1161	1132	-2%
V 3.3	27-Feb-19	27-Feb-19	871	13-Mar-19	997	947	-5%	27-Mar-19	1147	988	-14%	10-Apr-19	1325	1022	-23%
V 3.4	13-Mar-19	13-Mar-19	920	27-Mar-19	1147	988	-14%	10-Apr-19	1325	1022	-23%	24-Apr-19	1559	1052	-33%
V 3.5	27-Mar-19	27-Mar-19	1,020	10-Apr-19	1325	1103	-17%	24-Apr-19	1559	1165	-25%	8-May-19	1796	1226	-32%
V 3.6	10-Apr-19	10-Apr-19	1,177	24-Apr-19	1559	1390	-11%	8-May-19	1796	1601	-11%	22-May-19	1978	1870	-5%
V 3.7	24-Apr-19	24-Apr-19	1,360	8-May-19	1796	1705	-5%	22-May-19	1978	2049	4%	5-Jun-19	2118	2510	19%
V 3.8	8-May-19	8-May-19	1,591	22-May-19	1978	2144	8%	5-Jun-19	2118	2660	26%	19-Jun-19	2284	3360	47%
V 3.9	22-May-19	20-May-19	1,857	5-Jun-19	2118	2391	13%	19-Jun-19	2284	2851	25%	3-Jul-19	2463	3425	39%
V 3.10	5-Jun-19	5-Jun-19	2,016	19-Jun-19	2284	2324	2%	3-Jul-19	2463	2475	0%	17-Jul-19	2628	2607	-1%
V 3.11	19-Jun-19	19-Jun-19	2,181	3-Jul-19	2463	2486	1%	17-Jul-19	2628	2665	1%	31-Jul-19	2792	2842	2%
V 3.12	3-Jul-19	3-Jul-19	2,372	17-Jul-19	2628	2636	0%	31-Jul-19	2792	2806	1%	14-Aug-19	2930	2975	2%
V 3.13	17-Jul-19	17-Jul-19	2,515	31-Jul-19	2792	2771	-1%	14-Aug-19	2930	2933	0%	28-Aug-19	3057	3093	1%
V 3.14	31-Jul-19	31-Jul-19	2,690	14-Aug-19	2930	2933	0%	28-Aug-19	3057	3093	1%	11-Sep-19	3135	3252	4%
V 3.15	14-Aug-19	14-Aug-19	2,843	28-Aug-19	3057	3093	1%	11-Sep-19	3135	3252	4%	25-Sep-19	3193	3409	7%
V 3.16	28-Aug-19		2,997	11-Sep-19	3135	3241	3%	25-Sep-19	3193	3389	6%	9-Oct-19	3227	3534	10%
V 3.17	11-Sep-19	11-Sep-19	3,091	25-Sep-19	3193	3284	3%	9-Oct-19	3227	3391	5%	23-Oct-19	-	3490	-
V 3.18	25-Sep-19	24-Sep-19	3,175	9-Oct-19	3227	3302	2%	23-Oct-19	-	3368	-	6-Nov-19	-	3425	-
V 3.19	9-Oct-19	8-Oct-19	3,207	23-Oct-19	-	3293	-	6-Nov-19	-	3323	-	20-Nov-19	-	3346	-
V 3.20	23-Oct-19	22-Oct-19	3,250	6-Nov-19	-	3323	-	20-Nov-19	-	3346	-	4-Dec-19	-	3363	-

^{*}Actual case counts taken from CDC line list data; includes all confirmed and probable cases. ^ Models (from version 3.1 onward) were run using cases with imputed date-of-symptom onset. Including those with imputed date-of-symptom onset improves the model fit. The number of cases with imputed date-of-symptom onset is provided in the Methods section of the main text. Case count data from WHO line listing starting from version 3.16 (28-Aug-19).

APPENDIX 3: Log of recent changes to previous memo versions

(Full log of all changes to each previous memo version and changes in estimates over time are available upon request to: eocmodelingunit@cdc.gov)

Changes from V3.19 to 3.20

- Updated model fit with case report data provided by WHO in coordination with CDC IMS Ebola Response Epi-Lab Task Force available through 22 October 2019.
- Extended the projection to 23 April 2020.

Changes from V3.18 to 3.19

- Updated model fit with case report data provided by WHO in coordination with CDC IMS Ebola Response Epi-Lab Task Force available through 8 October 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming
 the following changed scenario for future changes in the proportion of cases effectively isolated such that onward
 transmission is prevented:
 - 59% of cases from 29 July 27 August 2019
 - o 65% of cases from 28 August 26 September 2019
 - o 65% of cases from 27 September 26 October 2019
 - 70% of cases from 27 October 25 November 2019
 - o 70% of cases from 26 November 25 December 2019
 - o 95% of cases from 26 December 2019 24 March 2020

Changes from V3.17 to 3.18

- Updated model fit with case report data provided by WHO in coordination with CDC IMS Ebola Response Epi-Lab Task Force available through 24 September 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming
 the following changed scenario for future changes in the proportion of cases effectively isolated such that onward
 transmission is prevented:
 - o 52% of cases from 29 June 28 July 2019
 - 58% of cases from 29 July 27 August 2019
 - 58% of cases from 28 August 26 September 2019
 - 58% of cases from 27 September 26 October 2019
 - o 64% of cases from 27 October 25 November 2019
 - 70% of cases from 26 November 25 December 2019
 - 95% of cases from 26 December 2019 23 February 2020

Changes from V3.16 to 3.17

- Updated model fit with case report data provided by WHO in coordination with James Fuller (CGH/DGHP) available through 10 September 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming the following changed scenario for future changes in the proportion of cases effectively isolated such that onward transmission is prevented:
 - 52% of cases from 29 June 28 July 2019
 - 54% of cases from 29 July 27 August 2019
 - o 54% of cases from 28 August 26 September 2019
 - o 54% of cases from 27 September 26 October 2019
 - 62% of cases from 27 October 25 November 2019*
 - o 70% of cases from 26 November 25 December 2019
 - 95% of cases from 26 December 2019 23 February 2020
 - *Note: Schedule for improvement in interventions schedule changed to start on 27 October 2019.
- Removed the sensitivity analysis scenario of a 20% improvement to the current/base analysis.

Changes from V3.15 to 3.16

- The source of data used to update model fit was changed from the CDC dataset to the WHO dataset. The data from these sources was very similar and this change had a negligible impact on model fitness and results.
- Updated model fit with case report data provided by WHO in coordination with James Fuller (CGH/DGHP) available through 27 August 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming the following changed scenario for future changes in the proportion of cases effectively isolated such that onward transmission is prevented:
 - 51% of cases from 29 July 27 August 2019
 - o 51% of cases from 28 August 26 September 2019
 - 60% of cases from 27 September 26 October 2019*
 - o 70% of cases from 27 October 25 November 2019
 - o 95% of cases from 26 November 2019 23 February 2020

*Note: Schedule for improvement in interventions schedule changed to start on 27 September 2019.

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ESTIMATION OF THE NUMBER OF MERCK EBOLA VACCINE DOSES NEEDED, THE DEMOCRATIC REPUBLIC OF CONGO

Ebola Vaccine Doses Estimation Memo V1.11

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BACKGROUND: A critical part of the public health response to the current outbreak of Ebola in the Democratic Republic of the Congo (DRC) is the deployment and administration of an Ebola vaccine (recombinant vesicular stomatitis virus—Zaire Ebola virus (rVSV-ZEBOV) vaccine, produced by Merck). The goal of this memo is to identify the amount of the Merck Ebola vaccine that may be needed in responding to this outbreak through 31 August 2020.

QUESTIONS: Using epidemiologic data from 08 Oct 2019, and three scenarios of the number of doses of Merck Ebola vaccine needed per case, as well as an alternative strategy using fractional dosing (for additional details, see Methods section), we answer the following questions:

- a. How many doses of Merck Ebola vaccine will be needed using each of three vaccination tactics assuming varying levels of effective isolation of Ebola cases?
- b. How does the estimated need for Merck Ebola vaccine compare to Merck vaccine supply between now and 31 August 2020?

Date: 11 October 2019

Authors: Centers for Disease Control and Prevention (CDC): Bishwa Adhikari, Brad Greening, Seonghye Jeon, Emily Kahn, Gloria Kang, Gabrielle Miller, Martin Meltzer, Health Economics and Modeling Unit (HEMU/DPEI); James Fuller (CGH/DGHP) Acknowledgements: Inger Damon (DHCPP/NCEZID/CDC); Dan Wolfe (BARDA/ASPR/HHS)

RED FLAG ALERT: The estimated proportion of cases in effective isolation has increased from 50% (v1.10) to 65% (v1.11, based on 09 October 2019 projections). Assuming no changes, the epidemic is now projected to end by 5 May 2020 with 3,410 total cases. Other outbreak indicators have shown small levels of improvement. Given the unknown degree of under-reporting of cases, however, these estimates of improvements in the control of the outbreak should be interpreted with caution. Assuming no changes in current control efforts, Merck Ebola vaccine supply will be adequate to meet demand, for each of the 3 vaccine use scenarios examined, through 31 August 2020.

SCENARIOS / BOTTOM LINE RESULTS

SCENARIOS: Epidemiological and Merck Ebola vaccine doses needed

A) Epidemiological scenarios: Total of 3 epidemiological scenarios

- Base case: Using reported Ebola cases up to 09 October 2019, we estimated that 65% of Ebola cases are
 effectively isolated (cf. Ebola Case Projection Memo v3.19). The base case is then estimated by
 projecting forward that 65% of Ebola cases are effectively isolated, and assumesing that there are no
 improvements in effectiveness of interventions going forward in time.
- Two sensitivity analyses assuming that, going forward from October 2019, 55% and 75% of cases have been effectively isolated, respectively.

B) Merck Vaccine doses needed per case under current vaccination guidelines of 1.0 ml doses; we estimate the Merck vaccine usage based on the following 3 vaccination tactics:

- Ring vaccination tactic: 96 doses per case (vaccinate contacts, contact-of-contacts, health care workers and frontline workers)
- Mixed-use vaccination tactic: 140 doses per case (70% of doses used in a ring vaccination tactic; 30% of doses used in a geographic based vaccination tactic)
- Geographic-based vaccination tactic: 240 doses per case

C) Merck Vaccine doses needed: Fractional dosing strategy: Repeat the above 3 vaccination tactics, adjusting estimate of Merck vaccine supply assuming all vaccinees receive 0.5 ml dose (so called "Guinea dose").

BOTTOM LINE RESULTS

Vaccination strategy: All vaccinees receive 1.0 ml dose:

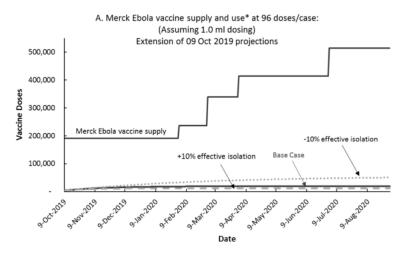
- Base case: With a ring vaccination strategy (96 doses per case), an estimated 19,609 Merck vaccine doses will be needed through 31 August 2020. With a mixed-use vaccination strategy (140 doses per case) or a geographic-based vaccination strategy (240 doses per case), an estimated 28,597 to 49,023 Merck vaccine doses will be needed through 31 August 2020, respectively (Figure 1 and Table 1).
- Lower limit of doses needed: Using a ring vaccination strategy and assuming that 75% of Ebola cases are effectively isolated (i.e., a 10% improvement in effective isolation from current estimates), 11,748 doses will be needed (Table 1).
- **Upper limit of doses needed:** Using a geographic-based vaccination and assuming that 55% of Ebola cases are effectively isolated (i.e., a 10% decrease in effective isolation), 126,053 doses will be needed.

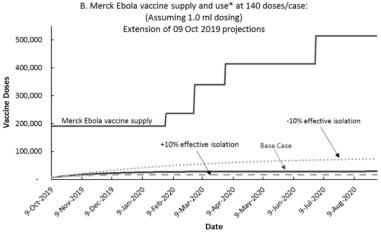
<u>Potential impact of dose-sparing strategy¹: All vaccinees receive 0.5 ml dose</u>Under all scenarios, current Merck Ebola vaccine supply will be adequate to meet demands by 31 August 2019.

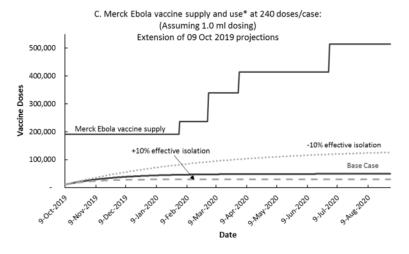
¹ Dose sparing calculations based on WHO SAGE recommendations of May 07, 2019 (see: https://www.who.int/immunization/policy/position_papers/interim_ebola_recommendations_may_2019.pdf).

MAIN TABLES AND FIGURES

Figure 1. Merck Ebola vaccine supply and demand: Based on 09 October 2019 case projections[†]







^{† 96} dose/ case = Ring vaccination tactic (vaccinate contacts, contact-of-contacts, health care workers and frontline workers); 140 dose/case = mixed-use vaccination tactic (30% of doses used in a geographic based vaccination tactic and 70% of doses used in a ring vaccination tactic); 240 dose/case = Geographic-based vaccination tactic.

^{*} Updated estimates of Merck vaccine supply provided by Dan Wolfe (OS/ASPR/BARDA) on 09 October 2019.

Table 1. Estimated number of Merck Ebola vaccine doses needed by 31 August 2020, with varying proportions of Ebola cases effectively isolated* and no improvement in effectiveness of interventions: Three vaccination tactics

(Based on cases reported up to 08 October 2019)

	Estimated cases:	Cases at	Additional cases:	Total doses needed by each tactic† (defined by doses/ case)			
Case estimate scenario**	31 Aug 2020	08 Oct 2019	09 Oct 2019 - 31 Aug 2020	Ring vaccination	Mixed-use vaccination	Geographic vaccination	
				96	140	240	
65% EFFECTIVE ISOLATION (BASE CASE)	3,411	3,207	204	19,609	28,597	49,023	
55% EFFECTIVE ISOLATION (10% DECREASE)	3,732	3,207	525	50,421	73,531	126,053	
75% EFFECTIVE ISOLATION (10% INCREASE)	3,329	3,207	122	11,748	17,133	29,371	

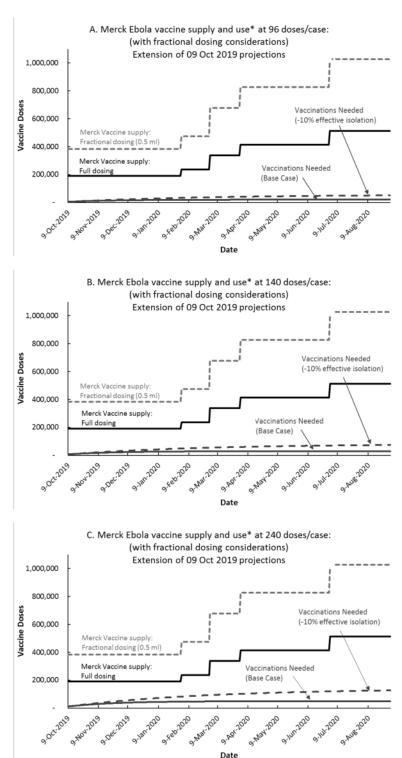
^{*} Effective isolation means preventing onward transmission of Ebola by ensuring that a patient is either physically isolated or their contacts are protected from infection. It is defined as identifying an Ebola patient and placing them in an Ebola Treatment Unit (ETU) or equivalent or vaccinating their contacts and contacts-of-contacts so as to prevent onward transmission of the disease. In addition, it can include minimizing the number of treatment facilities per case; vaccination of health care workers, frontline workers and community members; safe and dignified burials when needed.

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^{**} Estimates of future cases calculated using the following scenarios of cases effectively isolated. The higher (lower) the percent effectively estimated, the lower (higher) the estimates of future cases.

^{† 96} dose/ case = Ring vaccination tactic (vaccinate contacts, contact-of-contacts, health care workers and frontline workers); 140 dose/case = mixed-use vaccination tactic (30% of doses used in a geographic based and 70% of doses used in a ring vaccination tactic); 240 dose/case = Geographic-based vaccination tactic.

Figure 2. Merck Ebola vaccine supply and use: Using 09 October 2019 case projections: Impact of 0.5 ml dose-sparing strategy^{†*}



^{† 96} dose/ case = Ring vaccination tactic (vaccinate contacts, contact-of-contacts, health care workers and frontline workers); 140 dose/case = mixed-use vaccination tactic (30% of doses used in a geographic based vaccination tactic and 70% of doses used in a ring vaccination tactic); 240 dose/case = Geographic-based vaccination tactic.

^{*} Updated estimates of Merck vaccine supply provided by Dan Wolfe (OS/ASPR/BARDA) on 09 October 2019. The plots show maximum possible impact of using 0.5ml dose sparing tactic. See Methods for further details.

IMPORTANT CAVEATS

- Projections of cases of Ebola become more uncertain the farther out we project, as it is unknown how conditions may change over time.
- The results presented in this memo do not take into account corrections for underreporting. In late May, it was reported that an approximate 25% of cases were not being reported during that period (10, 11). However, there are no frequent reports of the degree of underreporting, indicating how such underreporting may have changed over the course-to-date of the epidemic.
- The estimated demand for Merck vaccines may not be realized because there may not be sufficient
 personnel and supplies to effectively deploy and administer the number of vaccines indicated. Inability
 to deploy and administer sufficient vaccine increases the risk of NOT being able to increase the
 effectiveness of interventions, and thus delaying the date at which the outbreak is controlled and
 ended.
- The estimates of demand for Merck vaccines assume that there will be a sufficient number of persons, at risk of contracting Ebola, willing to accept the vaccine. This assumption has not been tested.

EXPANDED RESULTS

Sensitivity analyses

Table 1 shows the number of Merck Ebola vaccine doses that would be needed for three vaccination tactics, assuming three alternative levels of effective isolation (55%, 65% and 75%). The number of vaccine doses needed is very sensitive to the proportion of Ebola cases that are effectively isolated.

Effective isolation of 55% of Ebola cases (10% lower than current estimate):

Between 50,421 (96 doses per case) and 126,053 doses (240 doses per case) will be needed, depending
on the vaccination tactic used. Merck Ebola vaccine supply will be adequate to meet demand by 31
August 2020 under this scenario.

Effective isolation of 75% of Ebola cases (10% higher than current estimate):

Between 11,748 (96 doses per case) and 29,371 doses (240 doses per case) will be needed, depending
on the vaccination tactic used. Merck Ebola vaccine supply will be adequate to meet demand by 31
August 2020 under this scenario.

METHODS

Data inputs

Table 2. Model inputs

·	Extension of 09 Oct 2019 case projections*
C	2 207
Cases reported as of 08 October 2019**	3,207
Estimated cases as of 31 August 2020	3,411
Current vaccination guidelines	
Assumed number of doses per case – lower estimate	96
Assumed number of doses per case – middle estimate	140
Assumed number of doses per case – upper estimate	240
Vaccine wastage rate	10%
Inflation factor§	20%
Impact of dose sparing tactics¶	
Multiplier if all persons vaccinated with 1/2 dose (0.5ml)	2

^{*}Ebola case estimates based on reported Ebola cases up to 08 October 2019, and then projecting forward assuming 65% of Ebola cases are effectively isolated (and thus prevent onward transmission), and that there are no improvements in effectiveness of interventions going forward in time.

Number of Merck vaccine doses per case

The lower estimate was set at 96 Merck vaccine doses per case (Table 2). This was calculated based on estimates that, as of 6 October 2019, approximately 233,366 people had been vaccinated and 3,205 Ebola cases had been reported to WHO². Thus, approximately 73 people have been vaccinated for each reported case. We added in a 10% vaccine wastage rate based on the expert opinion of those working closely with DRC's government. In addition, we allowed for 20% additional doses needed to vaccinate pregnant or lactating women, infants between the ages 6 months to 1 year, and people not identified through contact tracing or lost to follow-up arriving at 96 vaccine doses per case.

The upper estimate of 240 Merck vaccine doses per case (Table 2) is based on 200 doses as the approximate average between WHO (176 doses per case) and SAGE (230 doses per case). We added in a 20% increase in doses needed to vaccinate pregnant or lactating women, infants between the ages 6 months to 1 year, and people not identified through contact tracing or lost to follow-up arriving at 240 doses per case. Note that the WHO and SAGE estimates include 10% wastage.

^{**}To determine the future number of doses needed, these cases that occurred up to 08 October 2019 were subtracted from estimates of future cases (see Methods: Calculation of total number of doses).

[§] Factor to allow for vaccination of pregnant or lactating women, infants between the ages 6 months to 1 year, and people not identified through contact tracing or lost to follow-up. See main text for additional details.

[¶]See Methods for details of calculations of impact of dose sparing strategy.

² Data provided by WHO (https://www.who.int/emergencies/diseases/ebola/drc-2019/). As of 06 October 2019, it was reported that 233,366 persons had been vaccinated. Of those, 56,512 (24%) are contacts, 159,882 (69%) are contacts-of-contacts, and 50,035 (21%) are health care workers and frontline workers.

The estimate of 140 doses/case is a "mixed-use" tactic and is based on a mixture of the two other tactics, assuming 30% of doses are administered using a geographic-based tactic, and 70% are administered using a ring vaccination of contacts tactic. The estimate includes the 10% vaccine wastage that is included in the other two vaccination tactics.

Number of future Ebola cases

For the case projections, we used 3,207 cases (reported up to 08 October 2019) to estimate the expected number of Ebola cases up to 31 August 2020. Using methods described in Appendix 2, we first estimated that, in October 2019, 65% of cases were effectively isolated (i.e., isolated so that they did not cause onward transmission). We then estimated future cases up to 31 August 2020 by assuming that the estimate of 65% of cases effectively isolated would remain constant into the future (i.e., no improvement in effectiveness of interventions).

Number of Merck Ebola vaccine doses available

Information on the expected number of doses of Merck Ebola vaccine scheduled for delivery were provided by ASPR/BARDA (Figures 1 and 2) on 09 October 2019. These estimates include doses projected to be made available from October 2019 through July 2020.

Calculation of total number of doses needed

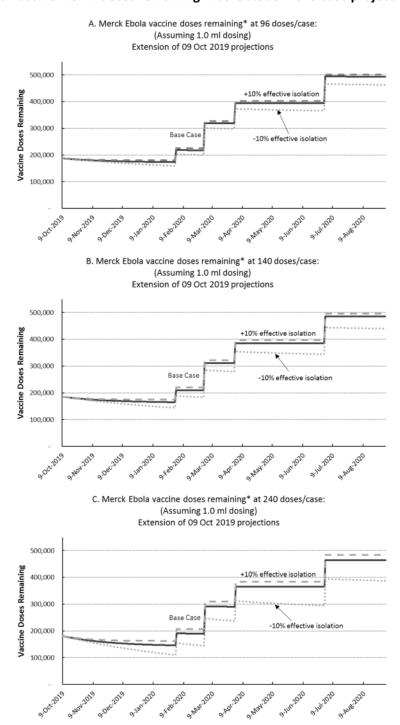
To calculate the future number of Merck Ebola vaccine doses needed, we took the estimated cumulative total cases and subtracted the 3,207 Ebola cases reported up to 08 October 2019 (Table 2). This provided the estimates of future cases. We then multiplied the estimated future number of cases by the three scenarios of vaccination tactics (i.e., by either 96 doses per case, 140 doses per case, or 240 doses per case).

Impact on Merck Ebola vaccine supply of dose sparing recommendations

To calculate the impact of all persons being vaccinated with ½ dose (0.5 ml per person vaccinated), we multiplied the remaining Merck vaccine supply by 2. Note that the plots shown in Figure 2 assume that all remaining Merck vaccine doses are subject to dose-sparing tactics. We did not consider the impact of logistics needed to implement such dose sparing strategy, nor the potential for additional wastage. Thus, the plots show maximum possible impact on vaccine supply.

APPENDIX 1: Supplemental Figures

Figure A1. Merck Ebola vaccine 1.0 ml doses remaining*§: 09 October 2019 case projections



^{*} Extension of 09 October 2019 case projections using reported case data up to 08 October 2019 and estimating future cases assuming 65% of cases will be effectively isolated and not infect other people (i.e., interventions are 65% effective).

[§] Vaccination strategies: The lower estimates of vaccine doses needed was set at 96 vaccine doses per case, representing a "ring vaccination" tactic. The upper estimate of 240 vaccine doses per case represents a "geographic-based" tactic. The estimate of 140 doses/case is a "mixed-use" vaccination tactic, and is based on a mixture of the two other tactics, assuming 30% of doses are administered using a geographic-based tactic, and 70% are administered using a ring vaccination tactic. All three vaccine use scenarios include an assumed 10% vaccine wastage and 20% increases in doses needed. See Table 1 and Methods for further details.

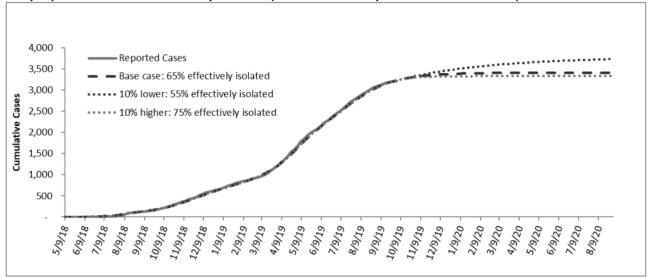
APPENDIX 2: Estimates of number of Ebola cases

We used the EbolaResponse model (available at http://dx.doi.org/10.15620/cdc.24900) to determine the proportion of Ebola cases in two categories:

- 1. Patients effectively isolated (i.e., either by placement in an Ebola Treatment Unit and/ or their contacts and contacts-of-contacts are effectively vaccinated, so as to prevent onward transmission), such that there is a reduced risk of disease transmission
- 2. Patients not effectively isolated, such that there is continued risk of onward transmission.

Estimates of the proportions of cases in these categories were produced by fitting the modeled data to the actual confirmed/probable cumulative case counts from DRC provided by the Goma Analytic Cell, which reports to the DRC Ministry of Health's Emergency Operations Center. These estimates are updated every two weeks. The estimates of Merck Ebola vaccine need shown in this memo are based on estimates of future cases produced on 09 October 2019, using data reported through 08 October 2019.

Figure A2. Projected cumulative number of Ebola cases through 31 August 2020, without improvements in the proportion of cases effectively isolated (based on case reports as of 08 Oct 2019)



*Ebola case estimates based on reported Ebola cases up to 08 October 2019, and then projecting forward assuming 65% of Ebola cases are effectively isolated (and thus prevent onward transmission), and that there are no improvements in interventions.

Table A1. Estimated number of cases and projected end date of Ebola outbreak, January 2019 – October 2019.

Outbreak Days	Dates	Estimated proportion of cases in effective isolation
241-270	31 Dec 2018 – 29 Jan 2019	50%
271-300	30 Jan – 28 Feb 2019	38%
301-330	1 Mar – 30 Mar 2019	33%
331-360	31 Mar – 29 Apr 2019	40%
361-390	30 Apr – 29 May 2019	57%
391-420	30 May – 28 June 2019	50%
421-450	29 June – 28 July 2019	52%
451-480	29 July – 27 Aug 2019	59%
481-510	28 Aug – 26 Sep 2019	65%
511-540	27 Sep – 26 Oct 2019	65%

METHODS: EbolaResponse Tool and Model overview

We built a spreadsheet-based model, called EbolaResponse, that allows a user to estimate the number of Ebola cases in the DRC and the proportion of cases that are effectively isolated such that onward Ebola transmission is prevented (1).

Type of model:

Our model, EbolaResponse, tracks patients through the following states: Susceptible (not yet infected); infected people incubating Ebola virus (but not yet infectious), infectious, recovered or dead (an SIIR model). The model is in effect, a Markov Chain model, and is similar in concept to that built by Chowell et al. (2). The one exception is that Chowell et al. included a state labeled "Exposure" and did not include our "incubating but not infectious category".

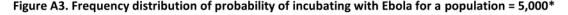
We use probabilities, drawn from reports of Ebola outbreaks, to model the daily movement of patients between and within the states. For example, for duration of incubation period, we adapted data from (3), which indicates the probability (likelihood) that patients will incubate 1, 2, 3 or more days, up to a maximum of 25 days (see below).

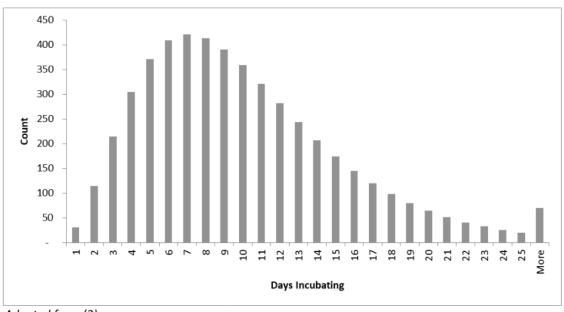
Progression only: A patient can only progress forward through the model, and can never regress (e.g., can never go from incubating back to susceptible). Nor can a patient skip a state (e.g., go from incubating to recovered, skipping infectious).

Community size: We used a community size of 78.7 million people (the estimated 2016 national population of the DRC, (3). The community size can be readily altered in the model.

Incubation period: We adapted published *probability distribution* data (3) to construct a gamma probability distribution of incubating with Ebola (Figure A3 and Table A2). We use a mean incubation period of 10.02 days (3).

Previous data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda (2), estimated mean incubation periods of 5.30 (SD 0.23) and 3.35 (SD 0.49) days, respectively. These appear to be lower than other published estimates (5, 6). Some of the differences may be attributable to different sub-types of the virus (5). Within the EbolaResponse model, the probability distribution for incubation can be readily changed to almost any structure desired, with an upper limit of 25 days incubation.





^{*} Source: Adapted from (3).

Table A2. Frequency distribution of probability of incubating with Ebola

Days	Frequency	Percent	Cumulative Percent	Days	Frequency	Percent	Cumulative Percent
1	31	0.6%	0.2%	14	207	4.1%	79.6%
2	114	2.3%	1.6%	15	174	3.5%	83.4%
3	215	4.3%	4.9%	16	145	2.9%	86.6%
4	305	6.1%	10.1%	17	120	2.4%	89.2%
5	371	7.4%	16.9%	18	98	2.0%	91.4%
6	409	8.2%	24.7%	19	79	1.6%	93.2%
7	421	8.4%	33.1%	20	64	1.3%	94.6%
8	413	8.3%	41.5%	21	51	1.0%	95.7%
9	391	7.8%	49.5%	22	60	1.2%	96.7%
10	358	7.2%	57.0%	23	50	1.0%	97.4%
11	321	6.4%	63.8%	24	45	0.9%	98.0%
12	282	5.6%	69.8%	25	35	0.7%	98.4%
13	243	4.9%	75.1%				
				Totals	5,000	100.0%	

Source: Adapted from (3).

Infectious period:

Based on WHO data, we used an infectious period of 6 days (3). This would include any time taken for a traditional burial. Chowell et al, using data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda, estimated mean infectious periods of 5.6 and 3.35 days, respectively (2). This period of 6 days includes all stages of symptomatic illness. It is true that patients may be symptomatic for longer periods (see 3) but being symptomatic is different than having the risk of onward transmission.

Note that the risk of onward transmission, absent effective isolation, does change as a patient becomes sicker (7, 8). However, EbolaResponse does not track individual patients. Instead, the model employs aggregate (e.g., mean) risk of onward transmission, aggregated over the entire period of symptomatic illness (1).

Potential risk: The following description from northern Uganda indicates the potential risk, due to possible contact with a victim's body fluids, posed by traditional burial of an Ebola victim: "A brief study indicated that once a person died, his or her paternal aunt (father's sister) was called to wash and prepare the body for burial. If the father did not have a sister, an older woman in the victim's patriline was asked to prepare the body. Generally, the woman removed the clothes from the body, washed the body, and dressed the deceased in a favorite outfit. At the funeral, all family members ritually washed their hands in a common bowl, and during open casket all were welcome to come up to deceased person and give a final touch on the face or elsewhere (called a love touch). The body was then wrapped in a white cloth or sheet and buried." (9)

Population "governor"

Although we explicitly don't include an "exposed" population element in the model, we do include a population "governor" that prevents the model from calculating more cases than the inputted population. This "over-calculation" could happen if one assumes that there is a relatively large percentage (defined below) of the population that become infected and are not effectively isolated, presenting a risk of onward disease transmission.

We programmed the governor by simply reducing the daily estimate of the persons newly infected proportionate to the cumulative reduction in the susceptible population, as follows:

Factor to reduce estimate of newly infected at Day t = (Model population – cumulative total of newly infected up to day (t-1)/ model population.

What this "governor" essentially does is to reduce, on a daily basis, the effective number of persons infected (i.e., effectively lowers the risk of transmission inputs shown in Table A3). In most instances, with "large populations," this

governor is unlikely to impact the calculations. The "governor" only begins to appreciably impact estimates (i.e., reduce them) when approximately 40% - 50% of the population have become infected.

Population and numbers initially infected

Country: The Democratic Republic of the Congo

Total Population: 78.7 million Number Initially Infected: 1

Distribution of patient by category over time

As explained in the main text, we split the patients into two categories of isolation, as follows:

- 1. Patients effectively isolated (i.e., hospitalized in ETCs or otherwise receiving medical care), such that there was reduced contact with others and a reduced risk of disease transmission.
- 2. Patients not effectively isolated, such that there was continued risk of onward transmission.

We explain how we calculate the percentage of patients in each category in the "goodness-of-fit" sub-section (below).

The risk of onward transmission from an Ebola patient to susceptible persons, by patient category, is shown in Table A3.

The distribution of patients into these categories affects the overall progress of the epidemic. The more patients in the "effectively isolated" category, the slower the progress of the epidemic because this category has a transmission rate of less than 1 person infected per infectious person. The distribution of patients into these categories, and how we changed those distributions over time, is shown in Table A1.

Table A3. Risk of onward transmission by category of patient: Values fitted to data compared to those in the literature

Patient category	Daily risk of onward transmission			Total numbers infected per infectious person**		
0 ,	Values fro	om literature (95% CI)†	Values used to fit	Values from		Model
			to data in DRC*	literature (95% CI)		estimates
Effectively	DRC	0.1134	0.03	DRC	0.4	0.18
isolated		(0.00001 - 0.5842)			(0 - 2.2)	
	Uganda	0.0017		Uganda	0.01	
		(0.0 - 0.918)			(0 - 3.5)	
No effective	DRC	1.0932	0.3	DRC	1.8	1.8
isolation		(0.00001 - 1.4281)			(0 - 2.3)	
	Uganda	0.066	-	Uganda	0.1	-
		(0.0 - 3.0367)			(0 - 3.2)	

^{*} These are the values used in the model in order to obtain a "good fit" to the data-to-date.

Source; Adapted from Legrand et al., 2007 (6).

Goodness-of-Fit:

Scenarios: Fitting to the existing data

For the original conception of the model, we essentially "reverse engineered" the following variables:

- i) Percentage of patients in each of the categories (effectively isolated; No effective isolation), with percentages changing over time (increments of 30 days) (see Appendix Table A1).
- ii) Risk of transmission by type of patient, with daily risk of onward transmission changing over time (increments of 30 days) (see Appendix Table A3).

^{**} Values of "Total number of persons infected per infectious person": When these values remain below 1 person infected per infectious person, then the epidemic will eventually end. For model: These are the equivalent values used to fit the model to the data, assuming 6 days of infectiousness (e.g., $0.3 \times 6 = 1.8$ persons infected per infectious person as per model fit)

[†] Values adapted from weekly values given by Legrand et al (6), from Ebola outbreaks in 1995 in Democratic Republic of Congo (DRC) (formerly Zaire), 2000 in Uganda. CI = Confidences Intervals.

^{††} We used, as proxies for "effective isolation," Legrand et al.'s measurements of "community component" (without burial) from DRC, as these were below 1.

For the purpose of this analysis, we held fixed the previously used values for risk of transmission and only varied the percentage of patients in each of the three categories. Essentially, we "balance" the percentages in "effectively isolated" and "NOT effectively isolated" until the plot of the model "fits" the plot of the actual data. Figure A4 shows the goodness-of-fit, comparing estimates of cases produced using EbolaResponse model to the reported confirmed and probable Ebola cases.

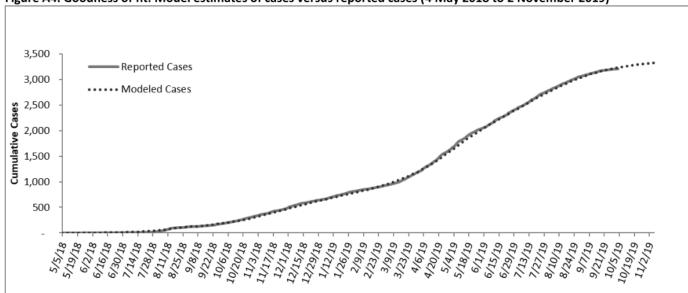


Figure A4. Goodness of fit: Model estimates of cases versus reported cases (4 May 2018 to 2 November 2019)

APPENDIX 3: Log of changes to previous memo versions

Changes from V1.10 to V1.11

- Extended the projections to 31 August 2020.
- Updated case projections using epidemiologic data available through 8 October 2019 provided by the Goma Analytic Cell, which reports to the DRC Ministry of Health's Emergency Operations Center.
- Updated estimates of vaccine supply using the information provided by Dan Wolfe (DHHS/ASPR/BARDA) on 9
 October 2019.
- Updated number of doses used per Ebola case based on number of cases and vaccinations provided as of 6
 October 2019.
- Clarified that the vaccine doses in this memo refer to Merck Ebola vaccine.

Changes from V1.9 to V1.10

- Updated case projections using epidemiologic data provided by DGHP on 03 July 2019
- Updated estimates of vaccine supply. Previously, estimates of Ebola vaccine were provided in terms of "total supply", absent any adjustments for doses shipped and/ or used. When considering estimates of need of doses in future, we made adjustments to vaccine supply by accounting for doses already administered. In this version, estimates of total remaining supply were given after adjustments made for doses already shipped (information provided by Gary Disbrow, DHHS/ASPR/BARDA). We thus adjusted our method of calculating future doses, by no longer accounting for doses administered-to-date (c.f., Figure 1 and 2).
- Removed 0.2 ml dose sparing strategy. Rationale: The likelihood of the 0.2ml dose being used in the field now
 appears remote.

Changes from V1.8 to V1.9

- Updated case projections using epidemiologic data provided by DGHP on 5 June 2019
- Updated number of vaccine doses used to those used as of 5 June 2019
- Updated number of doses used per Ebola case based on number of cases and vaccinations provided as of 5 June 2019, using a 10% vaccine wastage rate (changed from 20% wastage in previous memo versions), and inflation for vaccination of pregnant and lactating women and infants over 6 months of age
- Updated the dose-sparing strategy

Changes from V1.7 to V1.8

- Updated case projections using epidemiologic data provided by DGHP on 8 May 2019
- Updated number of vaccine doses used
- Added Figure showing estimated vaccine supply and dates of depletion using 2 dose-sparing strategies based on WHO SAGE committee recommendations
- Removed content pertaining to vaccination of pregnant/lactating women and infants

Changes from V1.6 to V1.7

- Updated case projections using epidemiologic data provided by DGHP on 10 April 2019
- Updated number of vaccine doses used
- Added table showing estimated date when vaccine supply is depleted for combinations of vaccination strategies and proportions of cases in effective isolation

Changes from V1.5 to V1.6

- Updated case projections using epidemiologic data provided by DGHP on 22 March 2019
- Included additional scenario(s) based on expanded vaccination guidelines to include pregnant and lactating women and children < 1 year of age.
- Updated estimates of vaccine supply (information provided by Gary Disbrow, BARDA)

Changes from V1.2b to V1.5

Updated case projections using data from Case Projection Memo 3.1 (dated 31 January 2019)

• Estimated vaccine needs based on 40%, 45%, 50% and 60% of Ebola cases being effectively isolated

Changes from V1.2a to V1.2b

• Updated estimates of vaccine supply (information provided by Gary Disbrow, BARDA) and extended projections to 1 November 2019

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Decision Brief: Increased Use of Targeted Geographic Vaccination Strategy in the Ebola Outbreak Response in the Democratic Republic of Congo (DRC)

Decision Point:

To reach consensus on increasing the utilization of targeted geographic vaccination to supplement ongoing ring vaccinations in areas of persistent Ebola transmission, with the goal of disrupting chains of transmission.

Introduction:

The current Ebola outbreak in North Kivu and Ituri Provinces is ongoing since 2018, with nine health zones still reporting cases within the past 21 days (as of Oct 31, 2019). The pre-emptive vaccination of front-line health care workers and the implementation of ring vaccination in DRC has been important in interrupting disease transmission. Vaccination efforts in DRC are consistent with April 2019 SAGE recommendations¹. The SAGE recommendations also include the use of targeted geographic vaccination when ring vaccination is substantially delayed, or accurate surveillance to support effective contact tracing is not possible.

Triggers for Targeted Geographic Vaccination: Currently, key "trigger conditions" have been met, in a health area such as Biakato Mines, that indicate the need to supplement ring vaccination activities with targeted geographic vaccination. These already met triggers include a notable percent of cases still being identified 4 or more days after symptom onset, active transmission with multiple unlinked chains of transmission, >50% of cases not known to be contacts at the time of identification, elevated risk of cases traveling to other locales and starting new chains of transmission, and difficulties due to ongoing lack of security that prevent contact tracing teams being able to adequately identify and follow contacts. These already activated triggers, singly or together, create delays in identification of clinical cases, the start of vaccination rings, and prevent rapid and thorough contact tracing efforts.

Current risk and epidemiological situation: There continues to be active transmission in DRC that is concentrated in Mandima health zone, particularly in the Biakato Mines health area. From Oct 2-22, 85% of cases had epidemiological links to Biakato mines in the Mandima health zone, with 36% of contacts known and followed, 24% of cases isolated early, and 32% community deaths compared to 44% contacts known and followed, 47% of cases isolated early and 15% community deaths nationwide. Given security and access challenges, improving contact tracing in order to implement effective ring vaccinations will be difficult and shifting resources to implementing a targeted geographic vaccination strategy is recommended.

This health area presents significant response challenges including mobile populations and lack of access due to security concerns; this has hindered timely case investigations, contact tracing, and public health response measures. These factors have resulted in delayed, low, and inaccurate contact tracing, causing difficulties in effectively implementing the ring vaccination strategy in these areas. Given the adverse effect on response activities, especially the challenges to contract tracing, targeted geographic vaccination should be considered.

Objectives for Strategy:

Increasing the use of a targeted geographic vaccination strategy with rVSV-ZEBOV (Merck) vaccine in areas with continued, persistent, active transmission with access or security issues is intended to:

Address challenges due to difficult and delayed contact tracing or delayed ability to implement or complete ring
vaccination by vaccinating a target population in a specific geographic area, creating a geographic "ring" around
a confirmed case.

¹ SAGE Recommendations on Vaccination against Ebola Virus Disease (EVD), April 4, 2019: https://www.who.int/immunization/sage/meetings/2019/april/6_SAGE_April_2019_Ebola_Henao.pdf?ua=1

- Address the challenge of under-reporting of cases and low contact tracing, as the ring vaccination strategy
 would have limited effectiveness in this scenario.
- Protect other health zones by breaking the chains of transmission due to a highly-mobile population, targeted
 geographic vaccination provides an opportunity to stop transmission and move closer to ending the outbreak.

Anticipated Impact and Outcomes:

By shifting resources from the current ring vaccination strategy to include targeted geographic vaccination, the response efforts would focus on creating a geographic ring around the "hotspot" in order reduce the risk of possible cases traveling outside the affected area and continuing transmission of EVD. As shown in map 2 in Appendix A, cases originating from the current hotspot in Biakato Mines are traveling to unaffected areas and continuing transmission. This shift in approach provides a way toward addressing the last cases of the outbreak.

Estimate of Resources Needed:

Target Population: The health zone of Mandima has a population estimated at 60,000 individuals with an estimated 21,789 individuals residing in Biakato Mines. The current resources, however, in country and logistical concerns suggest that targeting the entire health zone of Mandima is unrealistic.

Identifying numbers needed to vaccinate: Assuming 20-25 new cases per week, there will be approximately estimated 80-100 cases in one month. Further assuming, based on WHO SAGE recommendations, that targeted geographic vaccination results in 200-300 individuals vaccinated per case. Then, approximately **20,000 - 30,000 individuals** would be vaccinated by using a targeted geographic vaccination strategy in the Biakato Mines area.

Logistical and capacity considerations: Vaccination teams have administered up 1000-1500 vaccinations per day throughout DRC. Given that 80% of new cases are linked to Biakato Mines, if 80% of the current vaccination team resources were to be shifted to targeted geographic vaccination program in and around Biakato Mines, then approximately 800-1200 vaccinations could potentially be administered per day. Note this re-allocation of vaccination teams should not require hiring of notable numbers of additional vaccination team staff.

Timeframe: If human and logistical resources are shifted, as described above, to focus on targeted geographic vaccination of the Biakato Mines area, then it would take **4-6 weeks** to vaccinate the estimated 20,000 - 30,000 persons.

Vaccine Stock: As part of ongoing ring vaccination activities, 241, 601 individuals have been vaccinated as of October 22, 2019 with the remaining Merck vaccine doses in the field being 15,510². Based on current outbreak projections, an estimated 19, 609 Merck vaccine doses will be needed through Aug. 31, 2020 for the ring vaccination strategy and an estimated 28,597 to 49,023 doses will be needed for a geographic-based vaccination strategy³. The currently projected Merck vaccine stock should be sufficient for both ring and targeted geographic vaccination strategies to occur in DRC.

Proposed next steps:

With agreement on increasing the use of targeted geographic vaccination, coordination with the Ministry of Health, WHO, and other key partners will be needed to ensure their agreement, and then to create a more detailed implementation plan with standard operating procedures (SOPs) that is flexible in order to adapt to a dynamic context. The plan should include human resource needs, communications and community engagement strategies, as well as security and logistical considerations. The estimates and locations presented in this decision brief are exploratory estimates will need to be updated and scaled based on additional microplanning and information from the field.

² EVD DRC USG Sitrep 82_24_October_2019

³ Vaccine Memo v1.11 Oct 2019 supply late breaker

Appendix A: From Ebola DRC 09.00 AEM 20192410 final; DRC Data Pack from WHO

Map 1: Distribution of Ebola vaccine disease (EVD) in Mandima, Mambasa, Komanda, Oicha, and Lolwa Health Zones, reported between 02 October and 22 October 2019

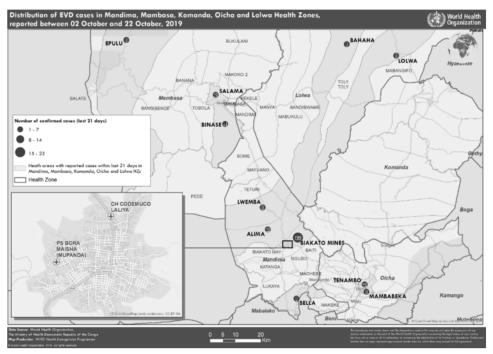
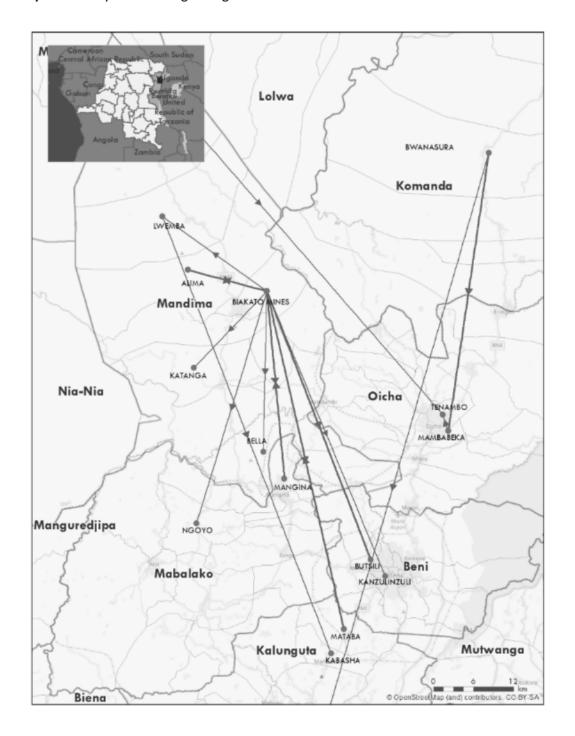


Table 1: Cases of Ebola vaccine disease (EVD) reported by Health Areas between 02 October and 22 October 2019

	No. of case	es reported (%)
Health area:		Last 21 days (2-22
village/quartier	Overall	Oct)
biakato_mine	85 (26%)	23 (85%)
lalia	9 (3%)	9 (33%)
mupanda	11 (3%)	6 (22%)
vubali	2 (1%)	2 (7%)
bangole	2 (1%)	1 (4%)
yosefu	1 (0%)	1 (4%)
other	16 (5%)	-
(missing)	44 (13%)	4 (15%)
alima	29 (9%)	2 (7%)
nduma	2 (1%)	2 (7%)
other/missing	27 (8%)	-
bela	4 (1%)	1 (4%)
nziapanda	1 (0%)	1 (4%)
other/missing	3 (1%)	-
lwemba	44 (13%)	1 (4%)
makale	1 (0%)	1 (4%)
other/missing	43 (13%)	-
katanga	45 (14%)	-
some	45 (14%)	-
biakato_mayi	22 (7%)	-
mayuano	18 (5%)	-
makeke	16 (5%)	-
other health areas	23 (7%)	-
Total	331 (100%)	27 (100%)

Map 2: Mobility of cases originating at Biakato Mines between 02 October and 22 October 2019



Ebola MCM Scientific Working Group Agenda

Tuesday, November 5, 2019; 10:30 AM (ET); Dial in - 202-774-2300 / Access code - 996 714 553

Meeting Objective: This meeting is intended to provide a forum for discussion of current and anticipated issues that will inform the HHS and PHEMCE strategy to meet the Medical Countermeasures (MCM) objectives outlined in section 5.0 of the HHS Ebola Response Improvement Plan Progress Report (Jan 2017). As such, areas of focus will be the use of MCMs to respond to the current outbreak in the Democratic Republic of the Congo and to ensure domestic preparedness, including:

- Fostering a joint understanding of MCM performance characteristics and developing USG viewpoint on proper use case for each
- Identifying gaps in MCM-related knowledge and defining the research agenda and plan to fill those gaps
- Identifying regulatory issues related to licensure and pre-licensure deployment of MCMs
- Projecting supply needs, outlining manufacturing options for MCMs and determining budgetary implications

All participants are strongly encouraged to suggest topics for discussion to ensure that this meeting is well positioned to meet the individual needs of each of the PHEMCE members. The Assistant Secretary for Preparedness and Response (ASPR) has confirmed that this meeting is being conducted under the PHEMCE Memorandum of Understanding and is subject to its requirements for confidentiality. Meeting agendas and a brief but comprehensive report summarizing the discussion and action items will be prepared by BARDA and provided to the ASPR following each meeting.

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Agenda:

- Meeting intro (DB, 5m)
- Geographic vaccination
 - o Intro to the DLG request (JR)
 - o Draft CDC Decision Brief (TH)
 - o Group Discussion
- Clinical isolate availability & virus stock production (DB, if time permits)
- NSC & DLG meetings update (CW, 5m)
- Wrap up and review of new action items (DB, 5m)

Action Items:

Action Item	Date Initiated	Responsible Agency or Individual	Resolution
Organize a group offline that can further discuss survivor studies	August 13	CDC, NIH	Active item
Reach out to WHO to discuss submission of compassionate use protocols	October 8	OGA	Active item
Raise Tier 1 vaccine availability issue with Mike Ryan and WHO	October 29	OGA	Active item

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    Sizemore, Christine (NIH/FIC) [E] <christine.sizemore@nih.gov>;
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Wholley, David (FNIH) [T] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afc96d003f9d4a41831a2d77566ed34e-david.wholl <dwholley@fnih.org>

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

Ella Nudell (b)(6) pgeorgetown.edu>;

Lamourelle, Gabrielle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cf3cb1a840847b3af0ea0c4d0d137c1-Lamourelle, <Gabrielle.Lamourelle@hhs.gov>;

Yarielka Arrieta (b)(6) ngmail.com>

Subject: USG-WHO MCM Dialogue Call

Date: 2020/05/20 15:21:32 Start Date: 2020/05/29 08:00:00 End Date: 2020/05/29 09:00:00

Priority: Normal Type: Appointment Location: WebEx/ Zoom

Kerr, Lawrence (HHS/OS/OGA); Weinberger, Collin (OS/OGA); Moudy, Robin (OS/OGA);

Chandrasekera, Ruvani (OS/OGA); Ferrey, Seth (OS/OGA); Aasen, Adam (HHS/OS/OGA); Snyder, Anne (HHS/OS/OGA); Wood, Rachel (HHS/OS/OGA); Olson, Leandra (HHS/OS/OGA); Schmeissner, Peter (HHS/OGA); LaHood, Natalie (OS/OGA); Smith, Steven T (Geneva); 'SmithSR1@state.gov'; Marks, Peter (FDA/CBER); Woodcock, Janet (FDA/CDER); Abdoo, Mark (FDA/OC); Disbrow, Gary (OS/ASPR/BARDA); Houchens, Christopher (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA);

'swaminathans@who.int'; 'ryanm@who.int'; 'simonsons@who.int'; 'simaom@who.int'; 'aylwardb@who.int'; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Helfand, Rita (CDC/DDID/NCEZID/OD); Hyde, Terri (CDC/DDPHSIS/CGH/GID); Cohn, Amanda

Attendees: (CDC/DDID/NCIRD/OD); Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP); Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE); Mair, Michael (FDA/OC); 'matthew.j.hepburn.civ@mail.mil'; Mcqueen, COL Anthony (HHS/IOS); Smith, Michael (MIL); 'sadam@fnih.org'; Lane, Cliff (NIH/NIAID) [E]; Gruber, Marion (FDA/CBER); Krause, Philip (FDA/CBER); Thomas, Ashley (FDA/CDER); 'borgesa@who.int'; Bugin, Kevin (FDA/CDER); Cho, David S (CBER) (FDA/CBER); Sizemore, Christine (NIH/FIC) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Donis, Ruben (OS/ASPR/BARDA); Blatner, Gretta (OS/ASPR/BARDA); Ayala, Ana (OS/OGA); Tracy Carson; 'NANNEI, Claudia'; 'MCLIESH, Wendy Maree'; Fernandez, Jose (OS/OGA); Burr, Mara (HHS/OS/OGA); Bleimund, Emily (OS/OGA); Tromberg, Bruce (NIH/NIBIB) [E]; Heemskerk, Jill (NIH/NIBIB) [E]; Ella Nudell; Lamourelle, Gabrielle (HHS/OS/OGA); Yarielka Arrieta

Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400-1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD Director Office of Pandemic and Emerging Threats

Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP Sender: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE>; Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE>

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Smith, Steven T (Geneva) < SmithST1@state.gov>;

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Tracy Carson /o=ExchangeLabs/ou=Exchange Administrative Group

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Fernandez, Jose (OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21d0317abb9f4d1bb2779f8b95826543-Fernandez, <Jose.Fernandez@hhs.gov>;

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

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'NANNEI, Claudia' <nanneic@who.int>;
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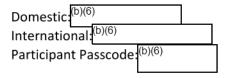
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Please join the USG-WHO Dialogue on COVID-19 MCMs. This week's call will be on Friday, July 10 from 9 - 9:45 am ET/ 1500 - 1545 Geneva.



If you have any questions, please contact Arnela.Lopez@hhs.gov and Ruvani.Chandrasekera@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

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Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400- 1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

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Туре:	OLE.CLASS.{00061055-0000-0000-C000-000000000046}

Please join the USG-WHO MCM Dialogue Call on July 24. This will be a biweekly call on Fridays from 8 to 9 am DC/Atlanta, 1400- 1500 Geneva.

Please find attached the slides, agenda, and notes from the previous meetings.

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If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD Director Office of Pandemic and Emerging Threats Office of Global Affairs U.S. Department of Health and Human Services

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'SmithSR1@state.gov' <SmithSR1@state.gov>;

Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>;

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'ryanm@who.int' <ryanm@who.int>;

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

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Subject: USG-WHO MCM Dialogue Call

Date: 2020/05/20 15:21:32

Start Date: 2020/05/29 08:00:00

End Date: 2020/05/29 09:00:00

Priority: Normal

Type: Appointment

Location: WebEx/ Zoom

Kerr, Lawrence (HHS/OS/OGA); Weinberger, Collin (OS/OGA); Moudy, Robin (OS/OGA);

Chandrasekera, Ruvani (OS/OGA); Ferrey, Seth (OS/OGA); Aasen, Adam (HHS/OS/OGA); Snyder, Anne (HHS/OS/OGA); Wood, Rachel (HHS/OS/OGA); Olson, Leandra (HHS/OS/OGA); Schmeissner, Peter (HHS/OGA); LaHood, Natalie (OS/OGA); Smith, Steven T (Geneva); 'SmithSR1@state.gov'; Marks, Peter (FDA/CBER); Woodcock, Janet (FDA/CDER); Abdoo, Mark (FDA/OC); Disbrow, Gary (OS/ASPR/BARDA); Houchens, Christopher (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA); 'swaminathans@who.int'; 'ryanm@who.int'; 'simonsons@who.int'; 'simaom@who.int';

'aylwardb@who.int'; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Helfand, Rita (CDC/DDID/NCEZID/OD); Hyde, Terri (CDC/DDPHSIS/CGH/GID); Cohn, Amanda

Attendees: (CDC/DDID/NCIRD/OD); Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP); Brooks, John T.

(CDC/DDID/NCRD/OD); Moltigornery, Joel Mr. (CDC/DDID/NCE2ID/DHCPP); Brooks, Jolini T. (CDC/DDID/NCHHSTP/DHPSE); Mair, Michael (FDA/OC); 'matthew.j.hepburn.civ@mail.mil'; Mcqueen, COL Anthony (HHS/IOS); Smith, Michael (MIL); 'sadam@fnih.org'; Lane, Cliff (NIH/NIAID) [E]; Gruber, Marion (FDA/CBER); Krause, Philip (FDA/CBER); Thomas, Ashley (FDA/CDER); 'borgesa@who.int'; Bugin, Kevin (FDA/CDER); Cho, David S (CBER) (FDA/CBER); Sizemore, Christine (NIH/FIC) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Donis, Ruben (OS/ASPR/BARDA); Blatner, Gretta (OS/ASPR/BARDA); Ayala, Ana (OS/OGA); Tracy Carson; 'NANNEI, Claudia'; 'MCLIESH, Wendy Maree'; Fernandez, Jose (OS/OGA); Burr, Mara (HHS/OS/OGA); Bleimund, Emily (OS/OGA); Tromberg, Bruce (NIH/NIBIB) [E]; Heemskerk, Jill (NIH/NIBIB) [E]; Ella Nudell; Lamourelle, Gabrielle

(HHS/OS/OGA); Yarielka Arrieta

Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400- 1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats

Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP Sender: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE>; Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE>

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Smith, Steven T (Geneva) < SmithST1@state.gov>;

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Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>;

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Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>;

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

Ella Nudell (b)(6) @georgetown.edu>;

Lamourelle, Gabrielle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cf3cb1a840847b3af0ea0c4d0d137c1-Lamourelle, <Gabrielle.Lamourelle@hhs.gov>;

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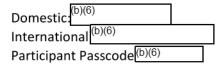
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্ダ繁篋倪㈱骨ホー縅戸䌹腶簾稿□啂剒梃程 Burr, Mara (HHS/OS/OGA) <Mara.Burr>; /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b229d23be0e24e03a3fd8244c450fb6b-Bleimund, E <Bleimund, Emily (OS/OGA)>; /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b229d23be0e24e03a3fd8244c450fb6b-Bleimund, E Tromberg, Bruce (NIH/NIBIB) [E]; <,>; <->; 6 EX; /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afc96d003f9d4a41831a2d77566ed34e-david.wholl Melencio, Cheryl (FNIH) [T]; /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Blatner, Gretta (OS/ASPR/BARDA)> Subject: USG-WHO Dialogue on COVID-19 MCMs Type: OLE.CLASS.{00061055-0000-0000-C000-000000000046}

Please join the USG-WHO Dialogue on COVID-19 MCMs. This week's call will be on Friday, July 10 from 9 - 9:45 am ET/ 1500 - 1545 Geneva.



If you have any questions, please contact Arnela.Lopez@hhs.gov and Ruvani.Chandrasekera@hhs.gov.

Larry Kerr, PhD Director Office of Pandemic and Emerging Threats Office of Global Affairs U.S. Department of Health and Human Services

> Kerr, Lawrence (HHS/OS/OGA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641554fc7843407585827af5898d9c26-Weinberger, <Collin.Weinberger@hhs.gov>;

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   Ella Nudell (b)(6) pgeorgetown.edu>;
   塅□萃塅勅乁薦秱卂伯涤塅勅乁葻襢麷义卉剔呁噉เ則問□衼甜籲輕②匳跡呌□乃刽鈴偉鼜呎□乃峂蔭牗
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Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400- 1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

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Ella Nudell (b)(6)
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Please join the USG-WHO MCM Dialogue Call on July 24. This will be a biweekly call on Fridays from 8 to 9 am DC/Atlanta, 1400- 1500 Geneva.

Please find attached the slides, agenda, and notes from the previous meetings.

When it's time, join your Webex meetin	g here.
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If you are a host, <u>click here</u> to view host in	tormation.
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If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD Director Office of Pandemic and Emerging Threats Office of Global Affairs U.S. Department of Health and Human Services

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Collin.Weinberger@hhs.gov 멥口ౚ越차묵口 <Collin.Weinberger.OS>;

Robin.Moudy@hhs.gov 멥口亞越치묵口 <Robin.Moudy.OS>;

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

Ella Nudell (b)(6) georgetown.edu>;
Lamourelle, Gabrielle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cf3cb1a840847b3af0ea0c4d0d137c1-Lamourelle, <Gabrielle.Lamourelle@hhs.gov>;

Yarielka Arrieta (b)(6) pgmail.com>;

Hinton, Denise (FDA/OC) < Denise. Hinton@fda.hhs.gov>

Subject: USG-WHO MCM Dialogue Call

Date: 2020/05/20 15:21:32 Start Date: 2020/05/29 08:00:00 End Date: 2020/05/29 09:00:00

Priority: Normal Type: Appointment Location: WebEx/ Zoom

> Kerr, Lawrence (HHS/OS/OGA); Weinberger, Collin (OS/OGA); Moudy, Robin (OS/OGA); Chandrasekera, Ruvani (OS/OGA); Ferrey, Seth (OS/OGA); Aasen, Adam (HHS/OS/OGA); Snyder, Anne (HHS/OS/OGA); Wood, Rachel (HHS/OS/OGA); Olson, Leandra (HHS/OS/OGA); Schmeissner, Peter (HHS/OGA); LaHood, Natalie (OS/OGA); Smith, Steven T (Geneva); 'SmithSR1@state.gov'; Marks, Peter (FDA/CBER); Woodcock, Janet (FDA/CDER); Abdoo, Mark (FDA/OC); Disbrow, Gary (OS/ASPR/BARDA); Houchens, Christopher (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA);

'swaminathans@who.int'; 'ryanm@who.int'; 'simonsons@who.int'; 'simaom@who.int'; 'aylwardb@who.int'; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Helfand, Rita (CDC/DDID/NCEZID/OD); Hyde, Terri (CDC/DDPHSIS/CGH/GID); Cohn, Amanda

Attendees: (CDC/DDID/NCIRD/OD); Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP); Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE); Mair, Michael (FDA/OC); 'matthew.j.hepburn.civ@mail.mil'; Mcqueen, COL Anthony (HHS/IOS); Smith, Michael (MIL); 'sadam@fnih.org'; Lane, Cliff (NIH/NIAID) [E]; Gruber, Marion (FDA/CBER); Krause, Philip (FDA/CBER); Thomas, Ashley (FDA/CDER); 'borgesa@who.int'; Bugin, Kevin (FDA/CDER); Cho, David S (CBER) (FDA/CBER); Sizemore, Christine (NIH/FIC) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Donis, Ruben (OS/ASPR/BARDA); Blatner, Gretta (OS/ASPR/BARDA); Ayala, Ana (OS/OGA); Tracy Carson; 'NANNEI, Claudia'; 'MCLIESH, Wendy Maree'; Fernandez, Jose (OS/OGA); Burr, Mara (HHS/OS/OGA); Bleimund, Emily (OS/OGA); Tromberg, Bruce (NIH/NIBIB) [E]; Heemskerk, Jill (NIH/NIBIB) [E]; Ella Nudell; Lamourelle, Gabrielle (HHS/OS/OGA); Yarielka Arrieta

Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400-1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD Director

Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP Sender: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE>; Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE>

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Smith, Steven T (Geneva) <SmithST1@state.gov>;

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Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>;

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Heemskerk, Jill (NIH/NIBIB) [E] <jill.heemskerk@nih.gov>;

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Lamourelle, Gabrielle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cf3cb1a840847b3af0ea0c4d0d137c1-Lamourelle, <Gabrielle.Lamourelle@hhs.gov>;

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Scharf, Sarah (NIH/OD) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7be58c4b45c4e978f7614d7d73425f9-sarah.schar <sarah.scharf@nih.gov>;

Hinton, Denise (FDA/OC) < Denise. Hinton@fda.hhs.gov>

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於對驗額λ誘練
型 Marks, Peter (FDA/CBER);

□ 麥頭口돈쬎劲 Woodcock, Janet (FDA/CDER);
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塅□萃塅勅乁薦秱卂伯涤塅勅乁葻襢麷义卉剔呁噉ӷ則問□衼甜籲輕②匳跡呌□乃刽鈴偉鼜呎□乃蛓ヲラセー
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" SMTP;
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'NANNEI, Claudia' <nanneic@who.int>;
'MCLIESH, Wendy Maree' <mclieshw@who.int>;
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 CC: 料愕終剏蒐稼址佈鍚呎 멥口を越入号口 <br/> <br/> <br/> 本のgesa@who.int>;
     Kevin.Bugin@fda.hhs.gov < Bugin, Kevin (FDA/CDER)>;
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     熱偔铒刷卉鏢蕌匮婉鑿剏锰鍲口佇V 멥口ౚៈ赫λ号口 <Sizemore, Christine (NIH/FIC) [Е]>;
     dwholley@fnih.org <Wholley, David (FNIH) [T]>;
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Kevin.Bugin@fda.hhs.gov < Bugin, Kevin (FDA/CDER)>;
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dwholley@fnih.org <Wholley, David (FNIH) [T]>;
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   欠篇勞仳葌蓻袴兄う薳帆膌垵□剔遂霉剁体N <EX>;
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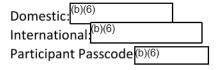
₭對鯵顯λ誘練
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Please join the USG-WHO Dialogue on COVID-19 MCMs. This week's call will be on Friday, July 10 from 9 - 9:45 am ET/ 1500 - 1545 Geneva.



If you have any questions, please contact Arnela.Lopez@hhs.gov and Ruvani.Chandrasekera@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

<Seth.Ferrey@hhs.gov>;

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Please join the USG-WHO MCM Dialogue Call. This will be a biweekly call on Fridays from 8 to 9 am ET/ 1400- 1500 Geneva.

We will share the final agenda and the WebEx or Zoom information.

If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

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Subject:	USG-WHO MCM Dialogue Call- WebEx Information Embedded
•	3
Туре:	OLE.CLASS.{00061055-0000-0000-C000-00000000046}

Please join the USG-WHO MCM Dialogue Call on July 24. This will be a biweekly call on Fridays from 8 to 9 am DC/Atlanta, 1400- 1500 Geneva.

Please find attached the slides, agenda, and notes from the previous meetings.

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If you have any questions, please contact Arnela.Lopez@hhs.gov and Ana.Ayala@hhs.gov.

Larry Kerr, PhD
Director
Office of Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services

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Robin.Moudy@hhs.gov 멥口ᡓ越치묵口 <Robin.Moudy.OS>;

Ruvani.Chandrasekera@hhs.gov 멥□虛越為号□ <Ruvani.Chandrasekera.OS>;

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Carson < CarsonTL@state.gov>;
nanneic@who.int 'NANNEI, Claudia' <nanneic@who.int>;
熱愕黯鮢墓慚鵑蛩□义T 멥□≧赫λ号□ <MCLIESH, Wendy Maree>;
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Bleimund, Emily (OS/OGA) <sip:emily.bleimund@hhs.gov>;
bruce.tromberg@nih.gov 멥□≈赫λ号□ <trombergbi.NIH>:
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=45a0d24180354f55a133fec3ade6c972-marion.grub Gruber,
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Ashley (FDA/CDER)>;
<'borgesa@who.int'>;
塅□萃塅勅乁藱梋卂伯涤塅勅乁藱襢麷义卉剔呁噉[則問□狡矠鯍軺②匳跡呌□乃刽鈴偉墓呎□乃卣钃敷
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<□き쨭秳躐調鎧呫>;
Ella Nudell 9 <d>;
Lamourelle, Gabrielle (HHS/OS/OGA) <sip:gabrielle.lamourelle@hhs.gov>;
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Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE> SentVia: Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE> Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre To: <Lawrence.Kerr@hhs.gov>; 'swaminathans@who.int' <swaminathans@who.int>; 'aylwardb@who.int' <aylwardb@who.int> Subject: USG-WHO MCM Cooperation Call Date: 2020/06/11 20:35:16 Start Date: 2020/06/12 08:00:00 End Date: 2020/06/12 08:30:00 Priority: Normal Type: Appointment Location: Conference line below

USG-WHO MCM Cooperation Call: Dr. Larry Kerr, Dr. Soumya Swaminathan and Dr. Bruce Aylward.

Domestic (b)(6)

International: (b)(6)

Participant Passcode: (b)(6)

Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE>; Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE>

Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre < Lawrence.Kerr@hhs.gov>; 'swaminathans@who.int' < swaminathans@who.int>; 'aylwardb@who.int' < aylwardb@who.int>

Sent Date: 2020/06/11 20:35:16

From: <Lawrence.Kerr@hhs.gov>

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.ive Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a41903d9dedb4a2d996190c9bea68982-Christie, A

<akc9@cdc.gov>;

Walke, Henry (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4fecd678cea4ee7a1436ed6ec669c27-Walke, Henr

Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge

<iad7@cdc.gov>

Subject: Fwd: How'd presser go?

Date: 2019/09/25 17:55:17

Priority: Normal Type: Note

Mike Ryan's slides below.

Sent from my iPhone

Begin forwarded message:

From: "Mciff, Colin (HHS/OS/OGA)" < Colin.Mciff@hhs.gov>

Date: September 25, 2019 at 4:35:49 PM EDT

To: "Grigsby, Garrett (HHS/OS/OGA)" < Garrett.Grigsby@hhs.gov >, "Kerr, Lawrence

(HHS/OS/OGA)" < Lawrence.Kerr@hhs.gov>

Subject: Re: How'd presser go?

These are the two slides Mike sent Garrett and me this morning in case they are what you need to save Garrett the trouble.

best, Colin

From: Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov>

Sent: Wednesday, September 25, 2019 10:24 PM

To: Kerr, Lawrence (HHS/OS/OGA) < Lawrence. Kerr@hhs.gov>

Cc: Mciff, Colin (HHS/OS/OGA) <Colin.Mciff@hhs.gov>

Subject: Re: How'd presser go?

Will send when I get home

Sent from my iPhone

On Sep 25, 2019, at 4:23 PM, Kerr, Lawrence (HHS/OS/OGA)

<Lawrence.Kerr@hhs.gov>wrote:

I was blown away by his synthesis of the 10 takeaway points! Rebecca is trying to get Mike R's IMS organogram. Can you get the Boss's? CDC has one so they are the best ones to synthesize and offer a consolidated position I think.

Sent from my iPhone

On Sep 25, 2019, at 4:04 PM, Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov>wrote:

Sent from my iPhone

Begin forwarded message:

From: "Pratt, Michael (OS/ASPA)" < Michael. Pratt@hhs.gov>

Date: September 25, 2019 at 3:04:55 PM EDT

To: "Grigsby, Garrett (HHS/OS/OGA)" < Garrett.Grigsby@hhs.gov>

Subject: Re: How'd presser go?

Great. Four or five q's. Mostly to Tedros but all good. Boss made "DRC is leading" point.

Sent from my iPhone

On Sep 25, 2019, at 2:47 PM, Grigsby, Garrett (HHS/OS/OGA)

<<u>Garrett.Grigsby@hhs.gov</u>>wrote:

Sent from my iPhone

Sender: <Lawrence.Kerr@hhs.gov>

Christie, Athalia (CDC/DDPHSIS/CGH/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a41903d9dedb4a2d996190c9bea68982-Christie, A

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<iad7@cdc.gov>

Sent Date: 2019/09/25 17:55:11

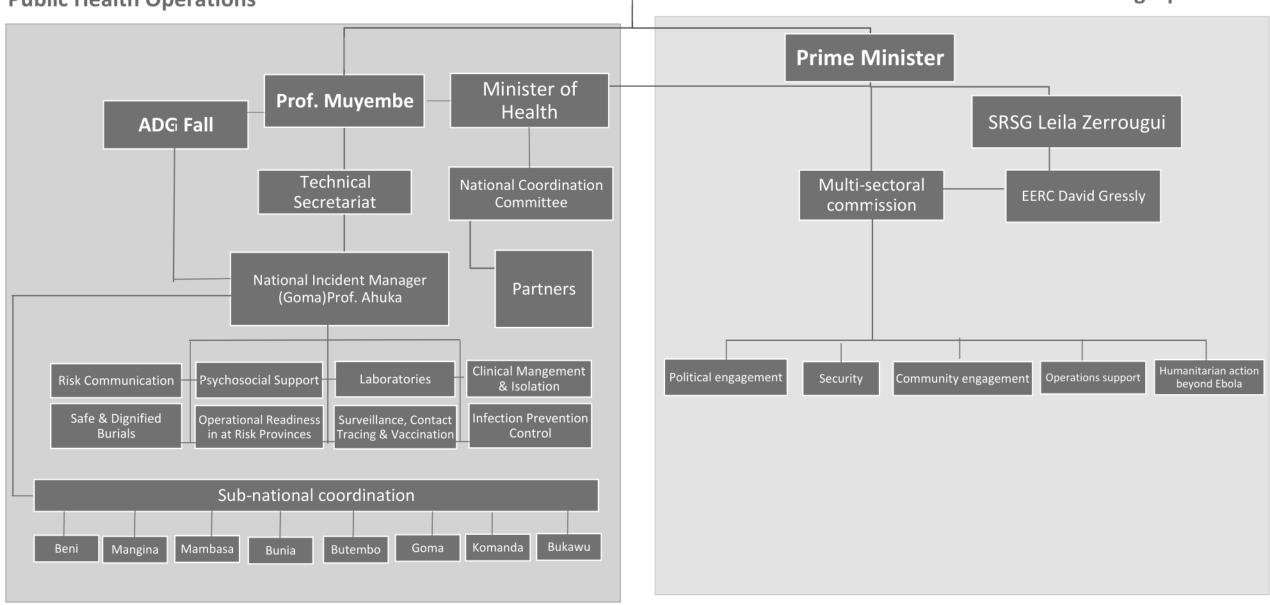
Delivered Date: 2019/09/25 17:55:17

Message Flags: Unsent

DRC President

Public Health Operations

Enabling Operations



Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>;

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Biggins, Julia E CTR (USA) < julia.e.biggins.ctr@mail.mil>;

Birnkrant, Debra B (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57a9d96c3a884fc0808702ed5d3a7b4c-debra.birnk <Debra.Birnkrant@fda.hhs.gov>;

Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f16dc874b53240f7a323b1246027e71c-rosalind.ca

Cho, David S (CBER) (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79853f418ac488c9cd10b70d1e2b0f1-david.cho.f <David.Cho@fda.hhs.gov>;

Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2063b181b77a49a4b498ee8b7afa7478-caitlin.cos <nrm9@cdc.gov>;

Wolfe, Daniel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01933911e406492fbd7f86e0235944d7-Wolfe, Dani <Daniel.Wolfe2@hhs.gov>;

Deussing, Eric (CDC/OD/OCS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e1290339b14ad6844f56b40d0c6661-eric.deussi <ncu0@cdc.gov>;

Diaz-Diaz, Carol (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b2b5f0685df417b9e2a0018c6fd251f-Diaz-Diaz, <Carol.Diaz-

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Higgs, Elizabeth (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3e542539154ce59df4bedbc8741ebf-elizabeth.h <ehiggs@niaid.nih.gov>;

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Gentles, Andrew (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd01d5eb6d814cbcb9d6547155eb7596-andrew.gent <Andrew.Gentles@fda.hhs.gov>;

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Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>;

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Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>;

Walldorf, Jenny A. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2813aaef1f94f96bb247826243e3811-jenny.walld

Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff8628c4e15948b3b03805d50c3d0eee-Kahn, Emily <ebk9@cdc.gov>;

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Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) <jennifer.m.kishimori.mil@mail.mil>;

Ledgerwood, Julie (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45778324d47644eeb9fced6acbf5108f-julie.marti <JUMARTIN@niaid.nih.gov>;

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Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>;

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Choi, Mary Joung (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f8d54090194cf7be8e49b80bca7328-mary.choi.c <whz2@cdc.gov>;

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Nelson Michael <nmichael@hivresearch.org>;

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Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US) (nathan.j.pawlicki.ctr@mail.mil) <nathan.j.pawlicki.ctr@mail.mil>;

Krause, Philip (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db30c21c61424ee0b278cee85f9a71f1-philip.krau <Philip.Krause@fda.hhs.gov>;

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Styrt, Barbara (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd3d53d2e3994f678050e141d6a0b9db-barbara.sty <Barbara.Styrt@fda.hhs.gov>;

Suzanne Mate <suzanne.e.mate.mil@mail.mil>;

Taylor, Kimberly (NIH/NIAID) [E] <kimberly.taylor3@nih.gov>;

Taylor, Marva (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34ad843b32e14d9fb5e825646336d169-Taylor, Mar

<Marva.Taylor@hhs.gov>;

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Thompson, Elizabeth (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebdef60dc3794a8db0daf295649d05f0-elizabeth.t <Elizabeth.Thompson@fda.hhs.gov>;

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Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>;

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

Date: 2019/10/13 10:31:51

Priority: Normal

Type: Note

Followed by:

Congo Plans to Start Using J&J's Ebola Vaccine From Next Month

Oct 12 2019, 9:48 PMOct 13 2019, 4:16 PMOctober 12 2019, 9:48 PMOctober 13 2019, 4:16 PM

(Bloomberg) -- The Democratic Republic of Congo will distribute a second vaccination for Ebola from Johnson & Johnson at the beginning of November.

The vaccine will first be distributed to two communes in Goma, the trading hub on the border with Rwanda, Dr. Jean-Jacques Muyembe, the head of the country's Ebola response effort, told reporters Saturday in the capital, Kinshasa. More than 64,000 people cross the border there each day, he said.

Johnson & Johnson will progressively ship about 200,000 doses of the vaccine to Rwanda and another 500,000 to Congo starting Oct. 18, Muyembe said.

"Our goal is to create an immunological curtain that will prevent the virus from leaving the infected zone to the uninfected zone," he said.

The Ebola outbreak, which was first announced in August 2018, has killed 2,146 people as of Oct. 10. Another vaccine manufactured by Merck &Co., has already been given to more than 230,000 people since August 2018.

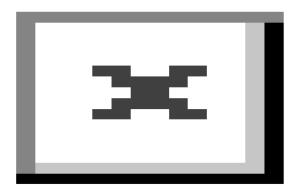
From: Kerr, Lawrence (HHS/OS/OGA) **Sent:** Sunday, October 13, 2019 10:27 AM

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Just out:

Rwanda planning massive vaccination campaign against Ebola





https://www.newtimes.co.rw/sites/default/files/styles/mystyle/public/main/articles/2019/10/12/dr-diane-gashumba.jpg

Dr Diane Gashumba, the Minister for Health, speaks at a recent meeting. / Sam Ngendahimana Rwanda is planning a big vaccination campaign against the Ebola Virus Disease (EBV) for adults, adolescents, and children aged two years living within the vicinity of a possible Ebola outbreak. A statement released after Thursday's Cabinet meeting indicates that the Minister of Health, Dr. Diane Gashumba, informed the Cabinet about this development.

By press time Saturday, however, efforts to get details such as when the campaign could start, how many people would be vaccinated, and what vaccine is to be used, from the Minister or media officers under the Ministry were futile.

The latest reports indicate that international efforts to halt the Ebola epidemic in DR Congo have made significant progress, with the virus now contained to a much smaller geographical area that is mainly rural in the east of the country.

The latest Ebola epidemic in the country began in August 2018 and it has killed 2,144 people, so far, according to the World Health Organisation.

In August, Rwanda started talks to acquire at least 100,000 doses of an Ebola vaccine for a mass vaccination campaign. At the time, the Ministry of Health confirmed that the government was fast-tracking negotiations to buy doses of an Ebola vaccine.

Malick Kayumba, the Spokesperson of the Ministry of Health confirmed recently that the deal was still under negotiations, and stressed that Rwanda was "ready to do whatever is possible to protect its citizens."

The BBC reported sometime back that more than 60,000 traders in eastern DR Congo who cross the border regularly into Rwanda and Uganda are to be vaccinated.

It was not clear when exactly the mass vaccination campaign would start and the cost associated as well as the type of vaccine to be used but media reports then suggested that the experimental vaccine was backed by international health experts, including the World Health Organisation.

The vaccine in question, the BBC reported, is produced by Johnson & Johnson, American multinational medical devices, pharmaceutical, and is different from the single-dose Merck vaccine that has been used

over the past year in DR Congo.

The World Health Organisation Director-General, Dr. Tedros Adhanom Ghebreyesus in August announced that they had an <u>Ebola vaccine that is more than 97 percent effective</u> and treatments that are more than 90 percent effective if used early enough.

Earlier, the UN health agency had announced that the co-sponsors of the Ebola therapeutics trial in DR Congo had announced advances that will bring patients a better chance of survival. <u>Two out of the four drugs</u> being tested were found to be effective in treating Ebola.

No case of Ebola has been reported in Rwanda but the government intensified preventive measures soon after the outbreak in DR Congo was confirmed.

In July, the WHO declared the Ebola crisis in the DR Congo a public health emergency of international concern (PHEIC), urging the international community to step up its support for a response.

The PHEIC is a formal declaration by the UN agency in charge of world health matters of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease.

In August, Rwanda and DR Congo Health Ministers set up joint strategies to prevent the spread of Ebola.

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

From: Boucher, David (OS/ASPR/BARDA)

Sorry, I lied about that being my last e-mail. Would be helpful if you had the link to the webex which is:

(b)(6)

Only going to be sharing the docs that have already been sent out so you won't miss anything if you'd rather not join the webex.

David

Sent: Tuesday, October 8, 2019 10:08 AM To: Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov) <amanda.zarrabian@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) < Ana. Ayala@hhs.gov >; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov) <rdc6@cdc.gov>; Cho, David S (CBER) (FDA/CBER) <<u>David.Cho@fda.hhs.gov</u>>; Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) <<u>nrm9@cdc.gov</u>>; Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov) < Daniel.Wolfe2@hhs.gov>; Deussing, Eric (CDC/OD/OCS) < ncu0@cdc.gov >; Diaz-Diaz, Carol (OS/ASPR/BARDA) < Carol.Diaz-diaz@hhs.gov >; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov) <ehiggs@niaid.nih.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Gentles, Andrew (FDA/CDER) <Andrew.Gentles@fda.hhs.gov>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Helen Schiltz (helen.schiltz@nih.gov) <helen.schiltz@nih.gov>; Hilary (NIH/NIAID) Marston [E] (hilary.marston@nih.gov) <hilary.marston@nih.gov>; Hughes, Craig (OS/ASPR/BARDA) < Craig. Hughes@hhs.gov >; Inger K. Damon (CDC/DDID/NCEZID/DHCPP) (iad7@cdc.gov) <iad7@cdc.gov>; Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>; Jenny A. Walldorf (CDC/DDPHSIS/CGH/GID) (igf4@cdc.gov) <igf4@cdc.gov>; Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) < ebk9@cdc.gov>; Karin (NIH/VRC) Bok [E] (karin.bok@nih.gov) <karin.bok@nih.gov>; Kayvon Modjarrad <kmodjarrad@hivresearch.org>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) < jennifer.m.kishimori.mil@mail.mil>; Lawrence Kerr (HHS/OS/OGA) (Lawrence.Kerr@hhs.gov) <Lawrence.Kerr@hhs.gov>; Ledgerwood, Julie (NIH/NIAID) [E] JUMARTIN@niaid.nih.gov>; Marinissen, Maria (HHS/OS/OGA)

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)
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Last e-mail from me. I've attached Karin Bok's slides that will go along with the manufacturing slides I sent out earlier this morning. I'll also try to share my screen through webex if you'd like to follow along that way.

David

From: Boucher, David (OS/ASPR/BARDA) Sent: Tuesday, October 8, 2019 9:07 AM To: Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov) <amanda.zarrabian@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>; Biggins, Julia E CTR (USA) < julia.e.biggins.ctr@mail.mil>; Birnkrant, Debra B (FDA/CDER) < Debra.Birnkrant@fda.hhs.gov >; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov) <rdc6@cdc.gov>; Cho, David S (CBER) (FDA/CBER) <David.Cho@fda.hhs.gov>; Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) <nrm9@cdc.gov>; Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov) < Daniel.Wolfe2@hhs.gov>; Deussing, Eric (CDC/OD/OCS) <ncu0@cdc.gov>; Diaz-Diaz, Carol (OS/ASPR/BARDA) <Carol.Diaz-diaz@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov) <ehiggs@niaid.nih.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Gentles, Andrew (FDA/CDER) <Andrew.Gentles@fda.hhs.gov>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Helen Schiltz (helen.schiltz@nih.gov) <helen.schiltz@nih.gov>; Hilary (NIH/NIAID) Marston [E] (hilary.marston@nih.gov) <hilary.marston@nih.gov>; Hughes, Craig (OS/ASPR/BARDA) <Craig.Hughes@hhs.gov>; Inger K. Damon (CDC/DDID/NCEZID/DHCPP) (iad7@cdc.gov) <iad7@cdc.gov>; Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>; Jenny A. Walldorf (CDC/DDPHSIS/CGH/GID) (igf4@cdc.gov) <igf4@cdc.gov>; Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) <ebk9@cdc.gov>; Karin (NIH/VRC) Bok [E] (karin.bok@nih.gov) <karin.bok@nih.gov>; Kayvon Modjarrad <kmodjarrad@hivresearch.org>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) < jennifer.m.kishimori.mil@mail.mil>; Lawrence Kerr (HHS/OS/OGA) (Lawrence.Kerr@hhs.gov) <Lawrence.Kerr@hhs.gov>; Ledgerwood, Julie (NIH/NIAID) [E] < JUMARTIN@niaid.nih.gov >; Marinissen, Maria (HHS/OS/OGA)

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Good morning, everyone. I've attached an updated version of the slide deck I sent last night. Couple of updates, couple of date errors corrected.

Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

David

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)
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Hello, everyone. I've attached a couple of documents for tomorrow's discussion.

For the first topic (manufacturing timelines), I've attached a brief deck summarizing the scheduled manufacturing of REGN-EB3 and mAb114 that is being supported by BARDA contracts. This was put together a couple of weeks ago obviously, but it is still an accurate summary of the current manufacturing schedule and the projected adds to the clinical supplies of REGN-EB3 and mAb114.

Second is a paper drafted by CDC that provides background and opens the discussion up for a potential recommendation that 16,000 1mL doses of the Merck vaccine be made available to Uganda, Rwanda and South Sudan. This discussion will be led by Rosalind Carter and Anita Samuel during the second half of tomorrow's meeting.

Thanks again and talk to you soon.

David

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Good morning, everyone. I've attached the agenda for tomorrow's meeting. As you can see, we have a pretty aggressive schedule so I'll look to start promptly at 10:30am and I've double checked the access code so we should be good on that front. I believe some slides might help the summary of the BARDA-supported manufacturing so I'll try to get a brief deck together and out to the group this evening.

On a housekeeping note, I believe I have everyone included and assigned correctly in the participant list. If there are any mistakes, please let me know. Also, if you're on this distribution list and do not plan to participate on a regular basis going forward, please let me know and I can update accordingly. Thanks!

David Boucher, PhD Chief, Antivirals & Antitoxins Division of CBRN Countermeasures

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Subject: Re: Ebola MCM WG: Merck update

Date: 2019/10/18 10:59:20

Priority: Normal

Type: Note

Major milestone for WHO-supported Ebola vaccine

18 October 2019 | **Geneva** - The World Health Organization (WHO) welcomes the European Medicines Agency (EMA) announcement recommending a conditional marketing authorization for the rVSV-ZEBOV-GP vaccine, which has been shown to be effective in protecting people from the Ebola virus.

Today's announcement by EMA, the European agency responsible for the scientific evaluation of medicines developed by pharmaceutical companies, is a key step before the European Commission decision on licensing. In parallel, WHO will move towards prequalification of the vaccine.

"The conditional authorization of the world's first Ebola vaccine is a triumph for public health,

and a testimony to the unprecedented collaboration between scores of experts worldwide," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "My deepest gratitude is to the studies' volunteers, researchers, health workers in Guinea, other countries and the Democratic Republic of the Congo who have put themselves at risk to ensure people are protected with this vaccine."

In the past five years, WHO has convened experts to review the evidence on various Ebola vaccine candidates, informed policy recommendations, and mobilized a multilateral coalition to accelerate clinical evaluations. The EMA review was unique in that WHO and African regulators actively participated through an innovative cooperative arrangement put in place by WHO, which will help accelerate registration for the countries most at risk.

A randomized trial for the vaccine began during the West Africa Ebola outbreak in 2015. When no other organization was positioned to run a trial in Guinea during the complex emergency, the government of Guinea and WHO took the unusual step to lead the trial.

A global coalition of funders and researchers provided the critical support required. Funders included the Canadian Government (through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre, Global Affairs Canada); the Norwegian Ministry of Foreign Affairs (through the Research Council of Norway's GLOBVAC programme); the Wellcome Trust; the UK government through the Department for International Development; and Médecins Sans Frontières.

The trial was successfully run using an innovative ring vaccination design. In the 1970s, this ring strategy helped to eradicate smallpox, but this was the first time that an experimental vaccine was evaluated this way.

WHO celebrates the commitment and sacrifices made by so many over the last five years, an international effort that led to this landmark moment in public health. The difficult and painstaking work was undertaken by a global team of researchers, health workers, partners, regulators, governments and field workers from logisticians to vaccinators, and finally, local communities. Together they overcame many obstacles. WHO also recognizes the Canadian government contribution to the early development of this vaccine.

Anticipating that in coming years there will be higher Ebola vaccine demand during and between outbreaks, WHO is working with Gavi, UNICEF and other partners to develop a Global Ebola Vaccines Security Plan, as increased supply capacity and multiple manufacturers will be needed in the short- to medium-term to meet this demand and ensure vaccine security.

There are 8 vaccines undergoing clinical evaluation. WHO continues to work with partners towards an internationally coordinated governing mechanism to ensure access according to risk criteria, and manage supply and stockpiles, especially as supply will remain limited until a full manufacturing capacity is established or other vaccines are licensed.

A roadmap aiming to accelerate prequalification and coordinate actions and contributions to the licensing and roll-out of the rVSV-ZEBOV-GP vaccine in African countries has been developed.

This announcement will not have an immediate effect on how the vaccine is accessed or administered in the Democratic Republic of the Congo, as licensing has not yet occurred, and licensed doses will only be available mid-2020. The vaccine will continue to be used in the country under a research protocol (also known as "expanded access" or "compassionate use"), and with the ring vaccination strategy.

In the current Ebola outbreak in the Democratic Republic of the Congo, more than 236,000 people have been vaccinated with rVSV ZEBOV GP donated by Merck to WHO, including more than 60,000 health and frontline workers in the Democratic Republic of the Congo and in Uganda, South Sudan, Rwanda and Burundi.

"This vaccine has already saved many lives in the current Ebola outbreak, and the decision by European regulator will help it to eventually save many more," said Dr Tedros, WHO Director-General. "I am proud of the role WHO has played, from supporting the research, to conducting the trial in Guinea in 2015."

Sent from my iPhone

On Oct 17, 2019, at 9:54 AM, Weinberger, Collin (OS/OGA) (CTR) < Collin.Weinberger@hhs.gov>wrote:

Dear All,

Ahead of the briefing at 12:30p today with Janssen/J&J, I wanted to recirculate the materials and dial in for the call. For those who are not able to join in person, we will be using webex to screen share the slides for Dr. Van Hoof's presentation (attached here and to calendar invite). I have also pasted the webex/dial-in information below.

Although we will NOT be discussing these today because we will have the Janssen/J&J presenting to the group, I wanted to also circulate the most recent HHS position and talking points around the Janssen vaccine (attached). NSC has asked HHS to revisit these talking points to consider whether we should change or update them given the impending vaccination campaigns with the Janssen vaccine in DRC and Rwanda. We will likely need to get back to NSC with an answer by early next week, so please consider this as we hear Dr. Van Hoof's presentation.

Best, Collin

Collin Weinberger, MPH
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Ebola MCM Scientific WG: Janssen/J&J Briefing on Ebola Vaccine and Vaccination Discussions in DRC, Rwanda, and Uganda

When: Thu, Oct 17 2019 12:30 pr	n (1 hour 30 minutes) Eastern Daylight Time (New York, GMT-04:00)
Host: Collin Weinberger	
Meeting Number:(b)(6)	

Voice connection:

- Meeting Server Main Number: (b)(6)
- • Access Code: (b)(6)

<Janssen Ebola vaccine HHS 17Oct19 Final.pdf>

<FINAL Background and Talking Points on Janssen Vaccine Trial 8-9-2019 for NSC.docx> Sender: <Lawrence.Kerr@hhs.gov> Weinberger, Collin (OS/OGA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641554fc7843407585827af5898d9c26-Weinberger, <Collin.Weinberger@hhs.gov>; Zarrabian, Amanda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c650b07917242129deb0f942bb4cc10-Zarrabian, <amanda.zarrabian@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80a408be55b14221a42c2b91002d6bf7-Ayala, Ana <Ana.Ayala@hhs.gov>; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Birnkrant, Debra B (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57a9d96c3a884fc0808702ed5d3a7b4c-debra.birnk <Debra.Birnkrant@fda.hhs.gov>; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f16dc874b53240f7a323b1246027e71c-rosalind.ca <rdc6@cdc.gov>; Cho, David S (CBER) (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79853f418ac488c9cd10b70d1e2b0f1-david.cho.f <David.Cho@fda.hhs.gov>; Recipient: Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2063b181b77a49a4b498ee8b7afa7478-caitlin.cos <nrm9@cdc.gov>; Wolfe, Daniel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01933911e406492fbd7f86e0235944d7-Wolfe, Dani <Daniel.Wolfe2@hhs.gov>; Deussing, Eric (CDC/OD/OCS) /o=ExchangeLabs/ou=Exchange Administrative Group

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Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>;

Hughes, Craig (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4ade4d09cb444bb995d03c84d1f0746-Hughes, Cra <Craig.Hughes@hhs.gov>;

Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge <iad7@cdc.gov>;

Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>;

Walldorf, Jenny A. (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2813aaef1f94f96bb247826243e3811-jenny.walld <iqf4@cdc.gov>;

Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff8628c4e15948b3b03805d50c3d0eee-Kahn, Emily <ebk9@cdc.gov>;

Bok, Karin (NIH/VRC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d1dc469e6684003a0a89b132e8b7916-karin.bok.n karin.bok@nih.gov;

Kayvon Modjarrad <kmodjarrad@hivresearch.org>;

Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) <jennifer.m.kishimori.mil@mail.mil>;

Ledgerwood, Julie (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45778324d47644eeb9fced6acbf5108f-julie.marti <jumartin@niaid.nih.gov>;

Marinissen, Maria (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d42fb4d94b041ee88e4f7dd5743e893-Marinissen, <Maria.Marinissen@hhs.gov>;

Gruber, Marion (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a0d24180354f55a133fec3ade6c972-marion.grub <Marion.Gruber@fda.hhs.gov>;

Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>;

Meltzer, Martin I. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d4e5aa77412403b9ae866e4c8312e79-Meltzer, Ma <qzm4@cdc.gov>;

Choi, Mary Joung (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f8d54090194cf7be8e49b80bca7328-mary.choi.c <whz2@cdc.gov>;

Merchlinsky, Michael (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a4736917274e3783b5570c29518cdf-Merchlinsky <Michael.Merchlinsky@hhs.gov>;

Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>;

Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62643d5586b14f1798171ce903c12ea4-Montgomery, <ztq9@cdc.gov>;

Moudy, Robin (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d421d3e0f6474bc3857583cfc5870d69-Moudy, Robi <Robin.Moudy@hhs.gov>;

Nelson Michael <nmichael@hivresearch.org>;

Bryant, Paula (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4fe56a126fc4da2a4a187dece3928e2-paula.bryan

Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US) (nathan.j.pawlicki.ctr@mail.mil)

<nathan.i.pawlicki.ctr@mail.mil>;

Krause, Philip (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db30c21c61424ee0b278cee85f9a71f1-philip.krau <Philip.Krause@fda.hhs.gov>;

Arthur, Ray (CDC/DDPHSIS/CGH/DGHP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=855f8ca30adc4a59906fd6647ac8371d-Arthur, Ray <rca8@cdc.gov>;

Helfand, Rita (CDC/DDID/NCEZID/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28a17ce03de24abbb3e9c9e1363c4017-Helfand, Ri <rzh7@cdc.gov>;

Sabourin, Carol (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46ae47e8f4b34a6e9d2804b44e192651-Sabourin, C <Carol.Sabourin@hhs.gov>;

Samuel, Anita (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9238fa3a950b4c118cad476c0ef01c40-anita.samue <kyp8@cdc.gov>;

Simon, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7d46815edf04bb28ac3ea25ff3d3268-Simon, Davi <David.Simon@hhs.gov>;

Styrt, Barbara (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd3d53d2e3994f678050e141d6a0b9db-barbara.sty <Barbara.Styrt@fda.hhs.qov>;

Suzanne Mate <suzanne.e.mate.mil@mail.mil>;

Taylor, Kimberly (NIH/NIAID) [E] <kimberly.taylor3@nih.gov>;

Taylor, Marva (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34ad843b32e14d9fb5e825646336d169-Taylor, Mar Marva.Taylor@hhs.gov;

Hyde, Terri (CDC/DDPHSIS/CGH/GID) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=653839b51d4442a7b5ad95e605761104-Hyde, Terri <tkh4@cdc.gov>;

Thompson, Elizabeth (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebdef60dc3794a8db0daf295649d05f0-elizabeth.t <Elizabeth.Thompson@fda.hhs.gov>;

Turley, Danielle (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=befe52d068424520bd5f5eddb942ff4d-Turley, Dan <Danielle.Turley@hhs.gov>;

Walke, Henry (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4fecd678cea4ee7a1436ed6ec669c27-Walke, Henr <hfw3@cdc.gov>;

Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>;

Yu, Yon C. (CDC/DDID/NCEZID/DPEI) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbdd97c36ce040d8adc6dc54932741bd-Yu, Yon C. <fkb8@cdc.gov>;

Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>;

Arboleda, Nelson (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d4af65b23fd452e9fbde0d8f6879142-Arboleda, N <Nelson.Arboleda@hhs.gov>;

Dubois, Ae (STATE.GOV) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54a41b227bb042cbada9163768f3b1f9-Ae.Dubois.s <duboisae@state.gov>;

Klein, Mackenzie (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb6bc8bed126402c8995ddbaf154ab72-Klein, Mack <Mackenzie.Klein@hhs.gov>;

Graham, Barney (NIH/VRC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2885576a25764ec1817bc73356fc9029-barney.grah

dgraham@mail.nih.gov>;

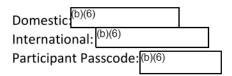
Poley, Gerald (FDA/CDER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1652fb2d5ebc405db14139a73d364c23-gerald.pole <Gerald.Poley@fda.hhs.gov>

Sent Date: 2019/10/18 10:59:20

Message Flags: Unsent

Kerr, Lawrence (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE> SentVia: Lopez, Arnela (OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE> Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre <Lawrence.Kerr@hhs.gov>; To: 'swaminathans@who.int' <swaminathans@who.int>; 'aylwardb@who.int' <aylwardb@who.int>; 'swaminathans@who.int' <swaminathans@who.int>; 'aylwardb@who.int' <aylwardb@who.int> Subject: USG-WHO MCM Cooperation Call Date: 2020/06/11 20:35:16 Start Date: 2020/06/12 08:00:00 End Date: 2020/06/12 08:30:00 Priority: Normal Type: Appointment Location: Conference line below

USG-WHO MCM Cooperation Call: Dr. Larry Kerr, Dr. Soumya Swaminathan and Dr. Bruce Aylward.



Kerr, Lawrence (HHS/OS/OGA) </0=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CE9DE2E7497472BB758F8FD6E262C86-KERR, LAWRE>;
Lopez, Arnela (OS/OGA) </0=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=505A8FE681584CA49E73F219976891AA-LOPEZ, ARNE>

Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre
<Lawrence.Kerr@hhs.gov>;

Recipient:
'swaminathans@who.int' <swaminathans@who.int>;
'aylwardb@who.int' <swaminathans@who.int>;
'swaminathans@who.int' <swaminathans@who.int>;
'aylwardb@who.int' swaminathans@who.int' <

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, Gl
<Garrett.Grigsby@hhs.gov>;
Lane, Cliff (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=11a174ee688e426392d98ba9cd5e1945-cliff.lane.
<CLANE@niaid.nih.gov>

Zebley, Kyle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81a0e4749994f969ff1063b9a3a0b1f-Zebley, Kyl
<Kyle.Zebley@hhs.gov>;
Oakley, Caitlin B. (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ee4c35534c4af9bdac46789c034790-Oakley, Cai
<Caitlin.Oakley@HHS.GOV>

Subject:

RE: CBS: Question for you

Date:

Type: Normal

(b)(5)		

From: Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>

Sent: Thursday, April 23, 2020 9:27 AM

To: Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Kerr, Lawrence (HHS/OS/OGA)

<Lawrence.Kerr@hhs.gov>

Cc: Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Oakley, Caitlin B. (OS/ASPA)

<Caitlin.Oakley@HHS.GOV>

Subject: FW: CBS: Question for you

Importance: High

Cliff and Larry,

Would y'all mind collaborating quickly and drafting a reply to CBS's question?

Larry has seen a version of this yesterday because DoS copied us, but now she is coming directly to HHS...

Thanks!

From: Zebley, Kyle (HHS/OS/OGA) < Kyle.Zebley@hhs.gov>

Sent: Thursday, April 23, 2020 12:14 AM

To: Kerr, Lawrence (HHS/OS/OGA) < Lawrence.Kerr@hhs.gov>; Elvander, Erika (OS/OGA)

<Erika.Elvander@hhs.gov>; Mciff, Colin (HHS/OS/OGA) <Colin.Mciff@hhs.gov>

Cc: Grigsby, Garrett (HHS/OS/OGA) < Garrett.Grigsby@hhs.gov>

Subject: Fwd: CBS: Question for you

Any thoughts on how to respond here?

Sent from my iPhone

Begin forwarded message:

From: "Oakley, Caitlin B. (OS/ASPA)" < Caitlin.Oakley@HHS.GOV>

Date: April 22, 2020 at 23:10:53 EDT

To: "Caputo, Michael (HHS/ASPA)" < Michael. Caputo@hhs.gov >, "McKeogh, Katherine

(OS/ASPA)" < Katherine. McKeogh@hhs.gov>

Cc: "Grigsby, Garrett (HHS/OS/OGA)" < Garrett.Grigsby@hhs.gov >, "Zebley, Kyle

(HHS/OS/OGA)" <Kyle.Zebley@hhs.gov>, "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>,

"Murphy, Ryan (OS/ASPA)" < Ryan.Murphy1@hhs.gov>

Subject: RE: CBS: Question for you

+ others. OGA--where's the best place to start on this? Looks WHO related. Thanks.

Caitlin B. Oakley

Deputy Assistant Secretary, National Spokesperson Office of the Assistant Secretary for Public Affairs U.S. Department of Health and Human Services caitlin.oakley@hhs.gov

From: Caputo, Michael (HHS/ASPA) < Michael. Caputo@hhs.gov>

Sent: Wednesday, April 22, 2020 11:08 PM

To: Oakley, Caitlin B. (OS/ASPA) < Caitlin.Oakley@HHS.GOV >; McKeogh, Katherine (OS/ASPA)

< Katherine. McKeogh@hhs.gov > Subject: CBS: Question for you

Please send this up the flagpole

Sent from my iPhone

Begin forwarded message:

From: "Brennan, Margaret" < Brennan M@cbsnews.com >

Date: April 22, 2020 at 10:28:46 PM EDT

To: "Caputo, Michael (HHS/ASPA)" < Michael. Caputo@hhs.gov>

Subject: Question for you

Hi Morgan Ortagus pointed me your way.

The WHO report says that China shared tissue samples of a 50 year old male Covid victim with the team that visited in February. This WHO team included 2 Americans. Why was that tissue sample not sufficient? I see Pompeo said that the virus samples were destroyed and not shared. This seems contradictory. Can you explain?

Regards,

Margaret Brennan Face the Nation Moderator Sr Foreign Affairs Correspondent 2027403062

Sent from my iPhone

Grigsby, Garrett (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, GI

<Garrett.Grigsby@hhs.gov>;

Lane, Cliff (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=11a174ee688e426392d98ba9cd5e1945-cliff.lane.

Recipient: <CLANE@niaid.nih.gov>;
Zebley, Kyle (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b81a0e4749994f969ff1063b9a3a0b1f-Zebley, Kyl

<Kyle.Zebley@hhs.gov>;

Oakley, Caitlin B. (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ee4c35534c4af9bdac46789c034790-Oakley, Cai

<Caitlin.Oakley@HHS.GOV>

Sent Date: 2020/04/23 09:34:46

Delivered Date: 2020/04/23 09:34:42

Message Flags: Unread Unsent

From: <Lawrence.Kerr@hhs.gov>

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.tive Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge <iad7@cdc.gov>;

Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>;

Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>;

OGA PET Ebola /o=ExchangeLabs/ou=Exchange Administrative Group

To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=34d6eb178464429aa80dca05d5c5c245-OGA-PET-Ebo <OGA-PET-Ebola@hhs.gov>;

Helfand, Rita (CDC/DDID/NCEZID/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28a17ce03de24abbb3e9c9e1363c4017-Helfand, Ri <rzh7@cdc.gov>;

Abram, Anna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5d498efef33e4d2ea760cacd22e8aeea-anna.abram. <Anna.Abram@fda.hhs.gov>;

Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks

(FYDIBOHF23SPDLT)/cn=Recipients/cn=df56588b970c43c8a9a2b9b31406746c-peter.marks <Peter.Marks@fda.hhs.gov>

Subject: Fwd: WHO CALL: Follow-up on Ebola Vaccine demand estimates and expansion of vaccine availability (Sept 19)

Date: 2019/09/16 10:41:27

Priority: Normal

Type: Note

FYI. Will forward the dial in info when I get it

Sent from my iPhone

Begin forwarded message:

From: "Carson, Tracy L (Geneva)" < CarsonTL@state.gov>

Date: September 16, 2019 at 5:20:46 PM GMT+3

To: "Smith, Steven T (Geneva)" < Smith ST1@state.gov >, "Martin, Rebecca

(CDC/DDPHSIS/CGH/OD)" <rtm4@cdc.gov>, "Kerr, Lawrence" <Lawrence.Kerr@hhs.gov>,

"Grigsby, Garrett (HHS/OS/OGA)" < Garrett.Grigsby@hhs.gov>

Cc: "Locus, Tiffany" <tiffany.locus@hhs.gov>, "Mciff, Colin (HHS/OS/OGA)"

<Colin.Mciff@hhs.gov>, "Gabrielle.Lamourelle@hhs.gov" <Gabrielle.Lamourelle@hhs.gov>,

"Levine, Maya" <maya.levine@hhs.gov>, "Wood, Rachel (HHS/OS/OGA)"

<Rachel.Wood@hhs.gov>

Subject: WHO CALL: Follow-up on Ebola Vaccine demand estimates and expansion of vaccine availability (Sept 19)

Dear all -

Sharing across HHS OGA and CDC given travel schedules – per Mike Ryan's email below – USG is invited to an informal "Ebola Vaccine demand estimates and expansion of vaccine availability " meeting/teleconference, to provide an update of our estimates, progress and challenges with the implementation of the ring vaccination and specific updates on the implementation of the SAGE

recommendations. The meeting/call will be on Thursday, Sept 19 from, 13:00-14:00 GVA. When the call-in number is sent out, I will forward to this group.

Best, Tracy

Tracy Carson

Tel: +41 (0) 22 749 4623 | Mobile: (b)(6)

(b)(6)

Unclassified

From: RYAN, Michael J. <<u>ryanm@who.int</u>> Sent: Monday, September 16, 2019 3:26 PM

To: Garrett.Grigsby@hhs.gov; OLX1@cdc.gov; Healy, Jenifer L. (AID/A) < ihealy@usaid.gov >; Cassayre,

Mark J (Geneva) < Cassayre MJ@state.gov >; Moley, Kevin E < Moley KE@state.gov >; julian.braithwaite@fco.gov.uk; D-Graymore@dfid.gov.uk; molyneux@dfid.gov.uk; Suzuki-

yasuhiro@mhlw.go.jp; hori-hiroyuki@mhlw.go.jp; naoki.akahane@mofa.go.jp;

<u>takato.koizumi@mofa.go.jp; wi-1-io@genf.auswaertiges-amt.de; Dagmar.Reitenbach@bmg.bund.de;</u> Bjoern.Kuemmel@bmg.bund.de; cab-andriukaitis-webpage@ec.europa.eu; drtheresa.tam@canada.ca

Cc: Carson, Tracy L (Geneva) < CarsonTL@state.gov >; wi-s1-io@genf.auswaertiges-amt.de;

Roisin.Fegan@fco.gov.uk; HENAO RESTREPO, Ana Maria < henaorestrepoa@who.int >; HOLDEN, Robert

Andrew < holdenr@who.int >; KABIR, Sophia < kabirso@who.int >; FARES, Christine Youssef

<faresc@who.int >

Subject: Follow-up on Ebola Vaccine demand estimates and expansion of vaccine availability

Dear Partners,

We would like to invite you or your delegated experts to an informal "Ebola Vaccine demand estimates and expansion of vaccine availability " meeting/teleconference, to provide an update of our estimates, progress and challenges with the implementation of the ring vaccination and specific updates on the implementation of the SAGE recommendations.

The meeting will take place on **19 September, from 13.00-14.00pm** in the lower SHOC room of WHO HQ. A dial-in number will be provided shortly.

If you have any specific items you would like to discuss or if you would like to present any information at the meeting, please let us know.

We would be pleased if you could participate or designate a focal point who should join the meeting.

Many thanks,

Dr Michael J Ryan Executive Director WHO Emergencies Programme World Health Organization Sender: <Lawrence.Kerr@hhs.gov>

Damon, Inger K. (CDC/DDID/NCEZID/DHCPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0200deb66dbc44f5aca3f26ed15cdc6a-Damon, Inge <iad7@cdc.gov>;

Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>;

Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>;

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Abram, Anna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group

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<Anna.Abram@fda.hhs.gov>;

Marks, Peter (FDA/CBER) /o=ExchangeLabs/ou=Exchange Administrative Group

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<Peter.Marks@fda.hhs.gov>

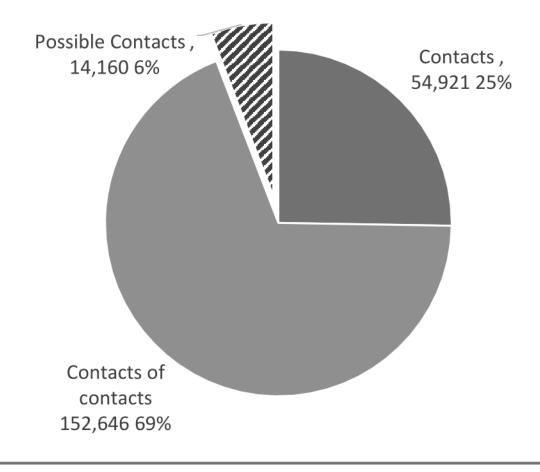
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The teams continue to vaccinate with rVSV ZEBOV GP (with informed consent) a large number of people at risk in the context of the outbreak Data as of September 15 2019

	Number	%
Total consented and vaccinated	221'841	
Contacts	54'921	24.7%
Contacts of contacts	152'646	69%
Possible Contacts	14'160	6.4%
Those vaccinated included the following		
populations:		
HCWs/FLWS	45'927	20.7%
Children 6-11 months	1'157	0.5%
Children 1-17 year old	72′101	32.5%
Pregnant women	796	0.4%
Breastfeeding Women	3'993	1.8%
Other groups	123'067	55.9%

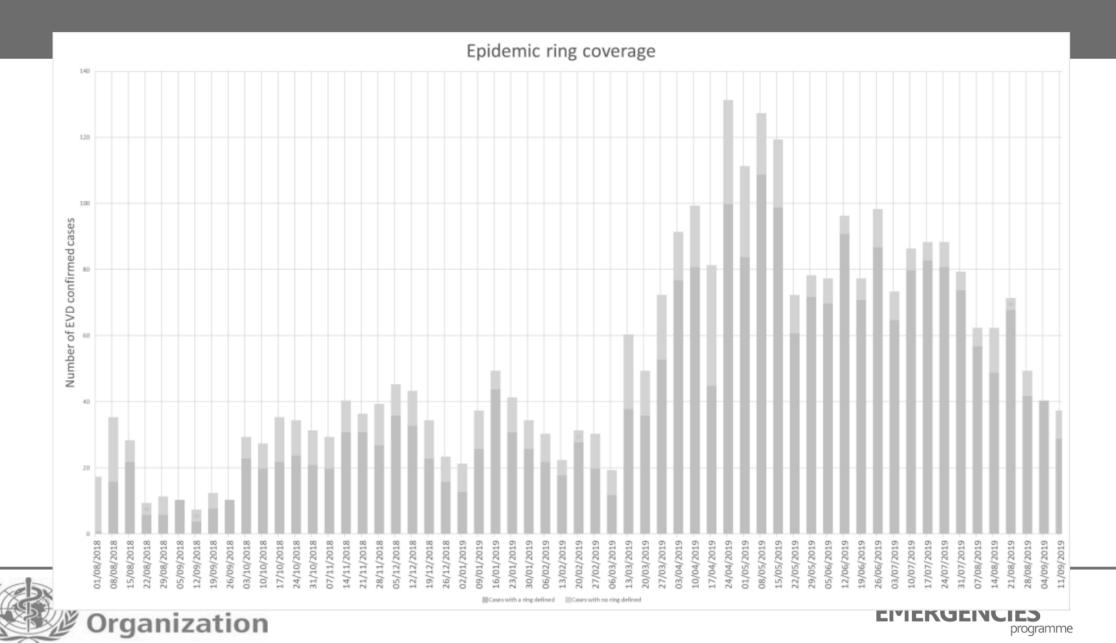
Total consented and vaccinated

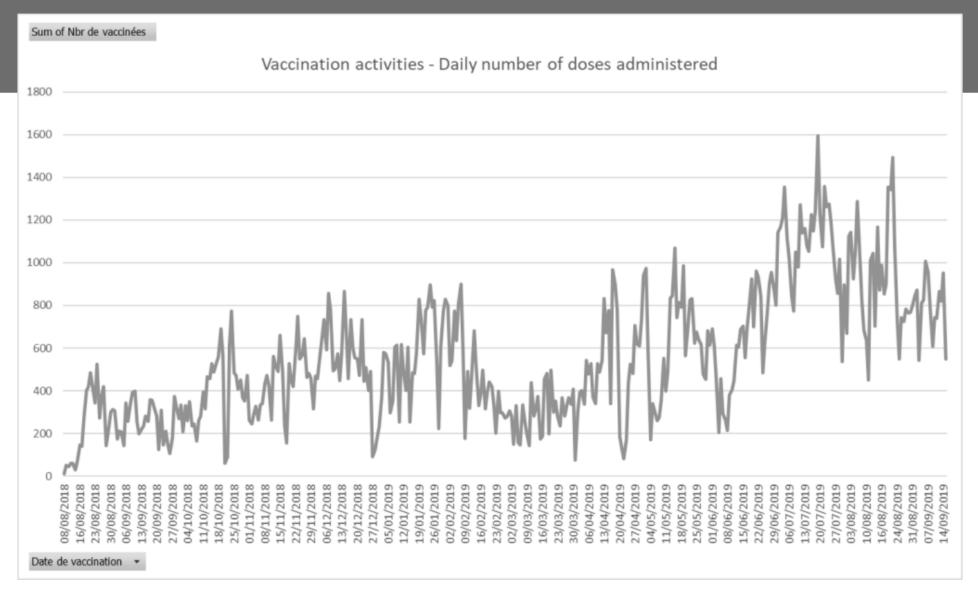






Cases of EVD with rings defined, ongoing or pendingNorth Kivu, South Kivu and

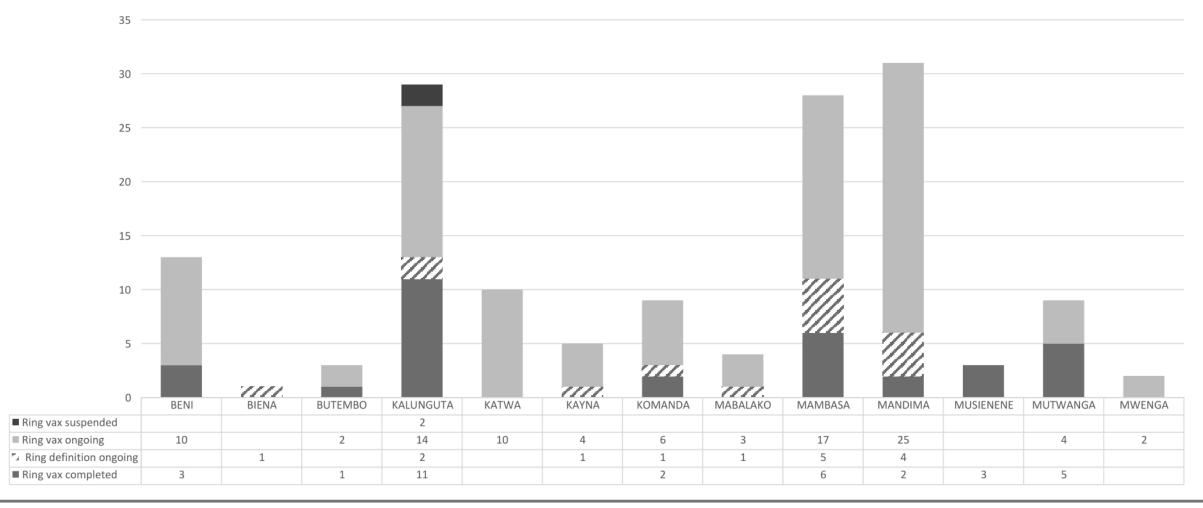








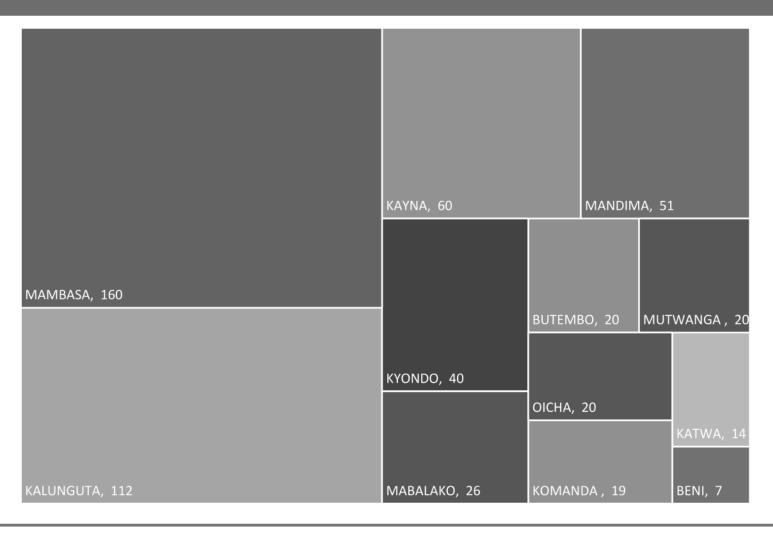
Cases of EVD with rings defined, ongoing or pendingNorth Kivu, South Kivu and







549 people vaccinated on Sept 15, 2019



HEALTH ZONE TOTAL VACCINATED BENI 7 HGR BENI 7 BUTEMBO 20 ITAV / CTE BUTEMBO 20 KALUNGUTA 112 CHAPELLE MASENZE 10 CH BUTUHE 27 CBCA / KABASHA 40 EGLISE CBCA KABASHA 35 KATWA 14 CS KIVIKA 4 CTE KATWA 2 STADE LIMBORO 8 KAYNA 60 HGR KAYNA 60 KOMANDA 19 NDIMO 19 KYONDO 40 CS KYONDO 40 MABALAKO 26 MAMBASA 160 CONGO YA SIKA 40 MADIDI 60 BANANA ECOLE 60 MANDIMA 51 CS LWEMBA 9 PS YASU NI BUANA 32 PS YASU NI BUANA 32 PS UNION FAIT LA FORCE 10		
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CAMP MILITAIRE 20 OICHA 20 MBIMBI 20	PS UNION FAIT LA FORCE	10
OICHA 20 MBIMBI 20	MUTWANGA	20
MBIMBI 20	CAMP MILITAIRE	20
	OICHA	20
Grand Total 549	MBIMBI	20
	Grand Total	549





USG-WHO DIALOGUE ON COVID-19 MCMs

FRIDAY, 24 JULY 2020

14:00 – 15:00 (Geneva) | 8:00 – 9:00 (DC/Atlanta)

1. Welcome and roll call

Ms. Ana Ayala, JD, LLM, Senior Global Health Officer, Pandemic and Emerging Threats, HHS/OGA

2. U.S. COVID-19 vaccine allocation/prioritization planning

Dr. Kathleen Dooling, MD, MPH, Co-Lead, Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Work Group, Centers for Disease Control and Prevention (CDC)

3. Discussion

All

4. Closing remarks and next steps

Ms. Ana Ayala, JD, LLM, Senior Global Health Officer, Pandemic and Emerging Threats, HHS/OGA

COVID-19 MCM USG-WHO MCM COOPERATION CALL

FRIDAY, 29 MAY 2020

15:00 - 16:00 (Geneva) | 9:00 - 10:00 ET

NOTES

Participants:

WHO: Dr. Soumya Swaminathan, Chief Scientist; Dr. Bruce Aylward, Secretariat for ACT Accelerator; Dr. Mariangela Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals; Dr. Sylvie Brian, Director for Global Infectious Hazard Preparedness; Dr. Vasee Moorthy, Coordinator for Research and R&D, WHO; Kate O'Brien, Director of the Department of Immunization, Vaccines and Biologicals; Emer Cooke, Director of Regulation of Medicines and other Health Technologies.

USG:

<u>CDC</u>: Amanda Cohn, Acting Director for the National Center on Birth Defects and Developmental Disabilities (NCBDDD); <u>FDA</u>: Mark Abdoo, Associate Commissioner for Global Policy and Strategy; David Cho, Senior Scientist for Emerging & Pandemic Threat Preparedness, CBER; Dr. Kevin Bugin, Director of Special Programs, Office of New Drugs, CDER, and OWS Therapeutics Program Manager; <u>NIH</u>: Steve Smith, US NIAID Liaison to Mission Geneva at WHO; Christine Sizemore, Director of the Division of International Relations, Fogarty International Center, NIH; <u>FNIH</u>: Mr. David Wholley, Senior Vice President, Research Partnerships, Foundation for the National Institutes of Health;

OGA: Larry Kerr, Director of Pandemic and Emerging Threats (PET); Emily Bleimund, Director of Trade and Health; Peter Schmeissner, Director of Europe/Eurasia; Anne Snyder, Senior Global Health Officer, Trade and Health; Collin Weinberger, Senior Advisor and Team Lead, PET; Robin Moudy, Senior Science Analyst, PET; Ana Ayala, Senior Global Health Officer, PET; Ruvani Chandrasekera, Senior Global Health Officer, PET; Leandra Olson, Senior Global Health Officer, Multilateral Affairs; Adam Aasen, Global Health Officer/Fellow, PET; Seth Ferry, Global Health Officer, PET; Natalie LaHood, Global Health Officer, PET

<u>Objective of USG-WHO Dialogue</u>: To support collaboration between USG/HHS and WHO on ensuring and addressing foreseeable global challenges to access to safe and effective MCMs, facilitating the exchange of information on the ACT Accelerator, Operation Warp Speed (OWS), and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

Act Accelerator Overview

<u>WHO Participants/Presenters</u>: Dr. Bruce Aylward, Secretariat for ACT Accelerator; Dr. Soumya Swaminathan

- Launched a month ago, there are four ACT pillars. Three focus on advancing R&D of vaccines, therapeutics and diagnostics respectively. The fourth pillar, Health Systems, is cross-cutting and considers the regulatory aspects, procurement, supplies, and other capacity and infrastructure country-facing work to ensure receipt and delivery of the product.
- In regular calls with NIH/NIAID so far have focused on therapeutics but not vaccines; e.g., harmonizing lab standards and global Data and Safety Monitoring Board (DSMB).
 - Have representatives from the Developing Countries Vaccine Manufactures Network (DCVMN) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

 Mechanism for fair allocation of products also being developed; using vaccines pillar as a test case.

Structure and Governance:

- Each pillar led by: two co-conveners working with WHO ADG-level person.
 - <u>Vaccines</u>: Co-chairs CEPI (Dr. Richard Hatchett), Gavi (Dr. Seth Berkley) + (WHO;
 Dr. Soumya in-house lead for vaccines)
 - Therapeutics: Co-chairs: UNITAID, Wellcome Trust + (WHO; Mariangela Simao inhouse lead)
 - <u>Diagnostics:</u> Co-chairs: Global Fund, FIND + (WHO; *ADG/Hannan Balkhy in house lead)*
 - Health Systems: Co-chairs- Global Fund, World Bank + (WHO)
- Each pillar is establishing its own structure and work plan with key deliverables for each partner agency.
- <u>Principals Group</u> created within each pillar, consisting of principals from each agency; runs
 the pillar's workplan and deconflicts when issues cannot be resolved within the pillar; any
 group can escalate to Principals Group. To date, issues have been resolved within the pillars
 and through consensus; no escalation yet. Within the vaccine pillar in particular, if there is
 conflict or resolution needed, COVAX Coordinating Mechanism (CCM) will bring in the
 Chairs of Boards of CEPI and GAVI to get things resolved and move as fast as possible
- Each pillar and the health systems group has specific work streams with authority for some decision-making; each led by an agency (e.g., for vaccines, R&D: CEPI; access & allocation: WHO; procurement & delivery: GAVI); disagreements escalated within the pillar.
- <u>Facilitation Group</u>: 1 enables engagement with key players on financing, access, and allocation issues; holds weekly mission briefings to update countries and IHR contact point countries (includes Taiwan) on ACT-A activities; Hub coordinates between the pillar and partners (likely donor countries).
 - Two special envoys appointed by DG Tedros: Sir Andrew Witty and Dr. Ngozi Okonjo-Iweala—have roles across pillars, advocacy, and integrating governments and outside institutional information.
 - ACT-A is aiming to be transparent. While there is no formal role for countries on daily
 activities, it is answerable to WHO Member States. Role of governments in providing input
 and contributing to decision-making is under discussion. WHO recognizes that WHO
 Member State concurrence on access frameworks and allocation principles will be critical.
 Civil society has also expressed interest in engaging
 - Trying to bring together a consolidated roadmap and set of priorities.

OWS Overview:

USG Participant/Presenter:

Dr. Kevin Bugin, OWS Therapeutics Program Manager

- OWS officially announced a week ago.
- Whole of USG effort to protect us from future COVID-19 issues, providing funding, increased coordination, regulatory support for diagnostics, vaccines, and therapeutics.
- <u>Structure</u>: Leads of each 'pillar' within OWS: Bruce Tromberg (NIH) for diagnostics, Matt Hepburn (Department of Defense, DOD) for vaccines, and Janet Woodcock (FDA) for

-

¹ As of June 2020, renamed to "ACT Accelerator Council."

therapeutics. Moncef Slaoui (Chief Scientist) reports to Board of Directors. Leads and 'pillars' report up to the HHS and DoD Secretaries.

- Considering OWS is as complex as ACT Accelerator, probably helpful to show slides in next call.
- <u>Diagnostics</u>: Working on strategies for diagnostics deployment and tracking to contain outbreak.
- Therapeutics: Working to develop things as quickly as possible and to support research for clinical evaluation, such as animal models and assays. Recognize that investment is needed for manufacturing considering types of therapeutics being and need for major scale up. Have been able to prioritize the most promising therapeutics in the wide space of the portfolio. Neutralizing mAb needs acceleration—immediate priority for first wave of effort (beyond immunomodulators and antivirals). Have two master protocols for patient groups to set up trials: inpatient and outpatient. Want randomized control trial to have adequate supply and enrollment.
- <u>Coordination:</u> Convened summit with CEOs of neutralizing Ab manufacturers. Working to determine their capacity and interest in joining a master protocol. Manufacturers enthusiastic and interested in working together (e.g., if only two candidates show promise, can manufacturing capacity built for other companies also be used to manufacture the two).

ACTIV Overview

USG Presenter: David Wholley, Manager of Research Partnerships Division, FNIH

- Foundation for the NIH is an independent 501c-3 to create private public partnerships to support the NIH. Structure allows for more flexibly to interact with industry.
- ACTIV launched on April 17, designed around four work streams: preclinical, therapeutic clinical testing, determining clinical trial capacity, and vaccines.
- <u>Preclinical</u>: Created an inventory of available master testing resources. Establishing a preclinical
 in vitro and in vivo testing network to test most promising reagents. Establishing publicly
 available database of standard procedures and data for preclinical compound data.
- Therapeutic clinical testing: Working closely with OWS. Accelerating COVID Therapeutic Trial (ACTT) and ACTT2.0. ACTT2.0 protocol currently enrolling and should reach full enrollment in 6 weeks. Looking to identify additional Contract Research Organizations (CROs) to link and support trial sites. Bayesian adaptive phase 2-3 progressive designed trials. Scheme for master protocol to test 3 immunomodulatory drugs (ACTIV1) not being tested elsewhere completed. Master protocol for anticoagulants being developed—working on establishing large trials. Planning de novo master protocol to test those not being done elsewhere—many antivirals likely.
- Determining clinical trial capacity: Conducted inside and outside NIH. Surveyed 49 major clinical trial networks, along with data on 8 CROs that can conduct vaccine and therapeutic sites. Resource for both clinical groups to identify sites and mechanisms and places to do the work. Identified 530 sites, mostly in the U.S. but some international. (June 15, 2020 Update: ACTIV has sent surveys to and collected information from 54 clinical trial networks representing over 600 sites. This information being used to prioritize sites for the master protocols to be launched through NIH networks and OWS.)
- <u>Vaccine clinical group</u>: Most work on planning master protocols and selecting sites moved to OWS, which group is supporting with an expert panel on safety questions, immune enhancement, endpoints, and policy on human challenge trials.

Potential Areas for Further Collaboration:

• WHO interested in useful collaboration and beyond what is available in the media: learning about U.S. efforts to minimize duplication, especially vaccines; since USG and WHO will be looking at

similar products, harmonizing trial protocols regarding clinical definitions, end points, and lab protocols; coordinating on immunogenicity assays and endpoints activities; and naming reference labs for data sharing.

 NIH noted harmonizing vaccine protocols is more complex since candidates are very different, but can help make the right connections to facilitate information sharing with ACT Accelerator vaccine working group. FNIH explained that work is being done on trial designs and endpoints, which has been taken over by OWS. NIAID would be the better avenue.

• WHO requests

- Information on vaccines, therapeutics, and diagnostics work in OWS would be helpful.
 - Sharing which vaccine candidates move to Phase 3 trials to know whether complimentary or duplicative.
 - NIH calls: Focused on therapeutics, but will be covering vaccines at some point; had a brief overview of ACTIV during last call.
 - Sharing information on specific clinical trial sites inside and outside the U.S. Interested in creating a global network of reference labs commissioned for standard assays, regardless of trial site location, to ensure compatibility and facilitate shipping of samples. WHO has mapped sites around the world for potential collaboration and to avoid duplication.
 - Sharing prioritization information on therapeutics—recognize that mAbs are
 most promising. Helpful if information on most promising candidates is publicly
 available since manufacturing capacity is a concern—many countries lack
 capacity.
 - FDA holds biweekly calls on comprehensive clinical trial database and can consider making public when leadership signs off the prioritization of candidates for therapeutics.
- Holding a videoconference on the organizational schemes on ACT, ACTIV and OWS, focusing on two main streams: coordination (including identifying partners) and technical issues. Can map out how to work together on these issues in next call

Summary of Next Steps

OGA to circulate notes and schedule a videoconference for next call to share the organizational structures ACT Accelerator, OWS, and ACTIV. Will need to determine the individual topics that need to be addressed in smaller technical teams.

USG-WHO DIALOGUE ON COVID-19 MCMs

FRIDAY, 10 JULY 2020

15:00 – 15:45 (Geneva) | 9:00 – 9:45 ET

NOTES

Participants:

WHO: Dr. Soumya Swaminathan, Chief Scientist; Dr. Bruce Aylward, Secretariat for ACT Accelerator; Dr. Mariangela Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals;

USG: ASPR: Christopher Houchens, Division Director of the CBRN Program; CDC: Rita Helfand, Senior Advisor for Science in NCEZID/Office of the Director; Terri Hyde, Global Immunization Division; FDA: David Cho, Senior Scientist for Emerging & Pandemic Threat Preparedness, CBER; Michael Mair; NIH: Christine Sizemore, Director of the Division of International Relations, Fogarty International Center, NIH; Sarah Scharf, Regional Program Director, Europe and Multilateral Organizations, Fogarty International Center, NIH; OGA: Garrett Grigsby, Director of Global Affairs; Larry Kerr, Director of Pandemic and Emerging Threats (PET); Emily Bleimund, Director of Trade and Health; OWS: Dr. Kevin Bugin, Director of Special Programs, Office of New Drugs, CDER, and OWS Therapeutics Program Manager;

<u>Objective of USG-WHO Dialogue</u>: To support collaboration between USG/HHS and WHO on ensuring and addressing foreseeable global challenges to access to safe and effective MCMs, facilitating the exchange of information on the ACT Accelerator and Operation Warp Speed (OWS).

ACT Accelerator Updates

Speakers: Dr. Bruce Aylward; Dr. Soumya Swaminathan; Dr. Mariangela Simão

- Dr. Bruce Aylward continues to coordinate the hub of ACT-A, ensuring the different pillars (vaccines [WHO lead: Dr. Soumya Swaminathan], therapeutics [WHO lead: Dr. Mariangela Simao], and diagnostics) have what they need to be successful.
- WHO noted that the case for ACT-A is stronger than it ever was as countries emerge from lockdowns and look to get societies and economies operational again.
- WHO believes the ACT-A infrastructure is working and has a good track record of
 accomplishments. ACT-A has integrated and leveraged existing international health architecture
 (such as GAVI and CEPI) to enable these accomplishments. More than 10 million tests have been
 procured, they are moving fast on securing therapeutics, and they have broad, growing vaccine
 portfolio.
- The launch of the COVID-19 Vaccine Global Access (COVAX) Facility under the vaccine pillar has resulted in a lot of interest, particularly from High- and Upper Middle-income countries.
- There has been positive engagement on the Global Allocation Framework that is being developed
 to ensure equitable and fair allocation of COVID-19 products through the ACT Accelerator. The
 access and allocation work stream has also started engaging with the therapeutics pillar to discuss
 how the framework can be expanded to address therapeutics in addition to vaccine. The
 Allocation Framework has also been shared with Victor Dzau at the National Academies of
 Science, Engineering, and Medicine (NASEM) at his request.
- Major challenges faced:

- Financing
- Nationalization of vaccine- The ACT Accelerator needs access to 2 billion doses of vaccine and buy-in to the COVAX Facility to make the construct work. ACT needs to address issues around nationalization of vaccine to avoid what happened during pandemic H1N1 where a select number of developed countries had access to vaccine before the rest of the world.
- WHO has good visibility of what is being developed by China.

Operation Warp Speed

Speaker: Dr. Kevin Bugin

- Therapeutics: Hoping to launch two master protocols later this month ACTIV2 for ambulatory patients (2 monoclonal products), ACTIV3 in inpatient setting (1-2 monoclonal products), tracking at least 5 other products that could be ready to enroll in August/September
- Vaccines: There is a lot of news coming out about the OWS products (AstraZeneca, Moderna, Janssen, Novavax), continue to support development and manufacturing scale-up
- Diagnostics: largely focused on expanding supply and availability across the U.S., and ensuring contact tracing in the U.S. to mitigate any additional outbreaks.

Summary of Next Steps

- OGA to follow-up within the USG and OWS on the action items below.
 - ACTION: WHO expressed interest in the U.S. and WHO sharing clinical intelligence in an effort to save time and put resources toward promising activities, especially as we've seen recently how AstraZeneca and Moderna have both pushed back their timelines. Of note, within the SOLIDARITY trial, WHO is looking at ways in coordination with CEPI to test vaccine candidates from smaller companies. WHO has good information exchange with NIH in terms of trial design, animal models, etc., and engaged with SWAT teams in CEPI.
 - ACTION: WHO would like to explore some "what if?" scenarios around availability of COVID-19 MCM products to help with planning COVID-19 MCM product allocation/distribution as products become available (e.g. in the event all vaccine development efforts are successful, how can WHO and US work to quickly and efficiently distribute surplus product?)
 - o **ACTION:** WHO would like to understand U.S. allocation plans and how they are being developed, particularly what CDC and NASEM's involvement is.
- OGA to circulate notes and schedule the next teleconference. The next call will focus on a deeper dive of the Allocation Framework (US will provide written input by July 14).

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

Date: 2019/10/13 10:33:00

Priority: Normal

Type: Note

Followed by:

Congo Plans to Start Using J&J's Ebola Vaccine From Next Month

Oct 12 2019, 9:48 PM Oct 13 2019, 4:16 PM October 12 2019, 9:48 PM October 13 2019, 4:16 PM

(Bloomberg) -- The Democratic Republic of Congo will distribute a second vaccination for Ebola from Johnson & Johnson at the beginning of November.

The vaccine will first be distributed to two communes in Goma, the trading hub on the border with Rwanda, Dr. Jean-Jacques Muyembe, the head of the country's Ebola response effort, told reporters Saturday in the capital, Kinshasa. More than 64,000 people cross the border there each day, he said.

Johnson & Johnson will progressively ship about 200,000 doses of the vaccine to Rwanda and another 500,000 to Congo starting Oct. 18, Muyembe said.

"Our goal is to create an immunological curtain that will prevent the virus from leaving the infected zone to the uninfected zone," he said.

The Ebola outbreak, which was first announced in August 2018, has killed 2,146 people as of Oct. 10. Another vaccine manufactured by Merck &Co., has already been given to more than 230,000 people since August 2018.

From: Kerr, Lawrence (HHS/OS/OGA)
Sent: Sunday, October 13, 2019 10:27 AM

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Just out:

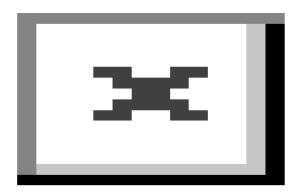
Rwanda planning massive vaccination campaign against Ebola



James Karuhanga By

James Karuhanga

Published: October 13, 2019 | Updated: October 13, 2019



https://www.newtimes.co.rw/sites/default/files/styles/mystyle/public/main/articles/2019/10/12/dr-diane-gashumba.jpg

Dr Diane Gashumba, the Minister for Health, speaks at a recent meeting. / Sam Ngendahimana Rwanda is planning a big vaccination campaign against the Ebola Virus Disease (EBV) for adults, adolescents, and children aged two years living within the vicinity of a possible Ebola outbreak. A statement released after Thursday's Cabinet meeting indicates that the Minister of Health, Dr. Diane Gashumba, informed the Cabinet about this development.

By press time Saturday, however, efforts to get details such as when the campaign could start, how many people would be vaccinated, and what vaccine is to be used, from the Minister or media officers under the Ministry were futile.

The latest reports indicate that international efforts to halt the Ebola epidemic in DR Congo have made significant progress, with the virus now contained to a much smaller geographical area that is mainly rural in the east of the country.

The latest Ebola epidemic in the country began in August 2018 and it has killed 2,144 people, so far, according to the World Health Organisation.

In August, Rwanda started talks to acquire at least 100,000 doses of an Ebola vaccine for a mass vaccination campaign. At the time, the Ministry of Health confirmed that the government was fast-tracking negotiations to buy doses of an Ebola vaccine.

Malick Kayumba, the Spokesperson of the Ministry of Health confirmed recently that the deal was still under negotiations, and stressed that Rwanda was "ready to do whatever is possible to protect its citizens."

The BBC reported sometime back that more than 60,000 traders in eastern DR Congo who cross the border regularly into Rwanda and Uganda are to be vaccinated.

It was not clear when exactly the mass vaccination campaign would start and the cost associated as well as the type of vaccine to be used but media reports then suggested that the experimental vaccine was backed by international health experts, including the World Health Organisation.

The vaccine in question, the BBC reported, is produced by Johnson & Johnson, American multinational medical devices, pharmaceutical, and is different from the single-dose Merck vaccine that has been used over the past year in DR Congo.

The World Health Organisation Director-General, Dr. Tedros Adhanom Ghebreyesus in August announced that they had an Ebola vaccine that is more than 97 percent effective and treatments that are more than 90 percent effective if used early enough.

Earlier, the UN health agency had announced that the co-sponsors of the Ebola therapeutics trial in DR Congo had announced advances that will bring patients a better chance of survival. Two out of the four <u>drugs</u> being tested were found to be effective in treating Ebola.

No case of Ebola has been reported in Rwanda but the government intensified preventive measures soon after the outbreak in DR Congo was confirmed.

In July, the WHO declared the Ebola crisis in the DR Congo a public health emergency of international concern (PHEIC), urging the international community to step up its support for a response.

The PHEIC is a formal declaration by the UN agency in charge of world health matters of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease.

In August, Rwanda and DR Congo Health Ministers set up joint strategies to prevent the spread of Ebola.

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Sent: Tuesday, October 8, 2019 10:22 AM

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Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Nelson Michael <nmichael@hivresearch.org>; Bryant, Paula (NIH/NIAID) [E] paula.bryant@nih.gov>; Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US) (nathan.j.pawlicki.ctr@mail.mil) <nathan.j.pawlicki.ctr@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Arthur, Ray (CDC/DDPHSIS/CGH/DGHP) <rca8@cdc.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Sabourin, Carol (OS/ASPR/BARDA) < Carol.Sabourin@hhs.gov >; Samuel, Anita (CDC/DDPHSIS/CGH/GID) <kyp8@cdc.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>; Styrt, Barbara (FDA/CDER) <Barbara.Styrt@fda.hhs.gov>; Suzanne Mate <suzanne.e.mate.mil@mail.mil>; Taylor, Kimberly (NIH/NIAID) [E] <kimberly.taylor3@nih.gov; Taylor, Marva (OS/ASPR/BARDA) <Marva.Taylor@hhs.gov>; Hyde, Terri (CDC/DDPHSIS/CGH/GID) <tkh4@cdc.gov>; Thompson, Elizabeth (FDA/CDER) < Elizabeth. Thompson@fda.hhs.gov>; Turley, Danielle (OS/ASPR/BARDA) <<u>Danielle.Turley@hhs.gov</u>>; Walke, Henry (CDC/DDID/NCEZID/DPEI) <<u>hfw3@cdc.gov</u>>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>; Yu, Yon C. (CDC/DDID/NCEZID/DPEI) <fkb8@cdc.gov> Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

Sorry, I lied about that being my last e-mail. Would be helpful if you had the link to the webex which is:

(b)(6)

Only going to be sharing the docs that have already been sent out so you won't miss anything if you'd rather not join the webex.

David

From: Boucher, David (OS/ASPR/BARDA)
Sent: Tuesday, October 8, 2019 10:08 AM

Sent: Tuesday, October 8, 2019 10:08 AM To: Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov) <amanda.zarrabian@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) < Ana. Ayala@hhs.gov >; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov) <rdc6@cdc.gov>; Cho, David S (CBER) (FDA/CBER) <David.Cho@fda.hhs.gov>; Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) <nrm9@cdc.gov>; Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov) < Daniel.Wolfe2@hhs.gov>; Deussing, Eric (CDC/OD/OCS) <ncu0@cdc.gov>; Diaz-Diaz, Carol (OS/ASPR/BARDA) <Carol.Diaz-diaz@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) < Gary. Disbrow@hhs.gov>; Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov) <ehiggs@niaid.nih.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Gentles, Andrew (FDA/CDER) <Andrew.Gentles@fda.hhs.gov>; Hassell, David (Chris) (OS/ASPR/IO) < David. Hassell@hhs.gov >; Helen Schiltz (helen.schiltz@nih.gov) < helen.schiltz@nih.gov >; Hilary (NIH/NIAID) Marston [E] (hilary.marston@nih.gov) <hilary.marston@nih.gov>; Hughes, Craig (OS/ASPR/BARDA) <Craig.Hughes@hhs.gov>; Inger K. Damon (CDC/DDID/NCEZID/DHCPP) (iad7@cdc.gov) <iad7@cdc.gov>; Inger-Marie Vilcins (ivilcins@hivresearch.org) <ivilcins@hivresearch.org>; Jenny A. Walldorf (CDC/DDPHSIS/CGH/GID) (igf4@cdc.gov) <igf4@cdc.gov>; Kahn, Emily B. (CDC/DDID/NCEZID/DPEI) <ebk9@cdc.gov>; Karin (NIH/VRC) Bok [E] (karin.bok@nih.gov) kayvon Modjarradkayvon Modjarradkmodjarrad@hivresearch.org; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (US) (jennifer.m.kishimori.mil@mail.mil) < jennifer.m.kishimori.mil@mail.mil>; Lawrence Kerr (HHS/OS/OGA) (Lawrence.Kerr@hhs.gov) <Lawrence.Kerr@hhs.gov>; Ledgerwood, Julie

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)
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Last e-mail from me. I've attached Karin Bok's slides that will go along with the manufacturing slides I sent out earlier this morning. I'll also try to share my screen through webex if you'd like to follow along that way.

David

From: Boucher, David (OS/ASPR/BARDA) Sent: Tuesday, October 8, 2019 9:07 AM To: Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov) <amanda.zarrabian@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) < Ana. Ayala@hhs.gov>; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov) <rdc6@cdc.gov>; Cho, David S (CBER) (FDA/CBER) <<u>David.Cho@fda.hhs.gov</u>>; Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) <<u>nrm9@cdc.gov</u>>; Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov) < Daniel.Wolfe2@hhs.gov>; Deussing, Eric (CDC/OD/OCS) <ncu0@cdc.gov>; Diaz-Diaz, Carol (OS/ASPR/BARDA) <Carol.Diaz-diaz@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov) <ehiggs@niaid.nih.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Gentles, Andrew (FDA/CDER) <Andrew.Gentles@fda.hhs.gov>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Helen Schiltz (helen.schiltz@nih.gov) <helen.schiltz@nih.gov>; Hilary (NIH/NIAID) Marston [E] (hilary.marston@nih.gov) <hilary.marston@nih.gov>; Hughes, Craig (OS/ASPR/BARDA) < Craig. Hughes@hhs.gov >; Inger K. Damon (CDC/DDID/NCEZID/DHCPP) (iad7@cdc.gov) <iad7@cdc.gov>; Inger-Marie Vilcins (ivilcins@hivresearch.org) <iuilcins@hivresearch.org>; Jenny A. Walldorf (CDC/DDPHSIS/CGH/GID) (igf4@cdc.gov) <igf4@cdc.gov>;

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)

Good morning, everyone. I've attached an updated version of the slide deck I sent last night. Couple of updates, couple of date errors corrected.

David

From: Boucher, David (OS/ASPR/BARDA) Sent: Monday, October 7, 2019 9:21 PM

To: Amanda Zarrabian (OS/ASPR/BARDA) (amanda.zarrabian@hhs.gov) amanda.zarrabian@hhs.gov">amanda.zarrabian@hhs.gov; Ayala, Ana (OS/ASPR/SPPR) Ana.Ayala@hhs.gov; Biggins, Julia E CTR (USA) julia.e.biggins.ctr@mail.mil; Birnkrant, Debra B (FDA/CDER) Debra.Birnkrant@fda.hhs.gov; Carter, Rosalind J. (CDC/DDPHSIS/CGH/GID) (rdc6@cdc.gov; Cho, David S (CBER) (FDA/CBER) David.Cho@fda.hhs.gov; Cossaboom, Caitlin (CDC/DDID/NCEZID/DHCPP) nrm9@cdc.gov; Daniel Wolfe (OS/ASPR/BARDA) (Daniel.Wolfe2@hhs.gov; Deussing, Eric (CDC/OD/OCS) ncu0@cdc.gov; Diaz-Diaz, Carol (OS/ASPR/BARDA) Carol.Diaz-diaz@hhs.gov; Disbrow, Gary (OS/ASPR/BARDA) Gary.Disbrow@hhs.gov; Elizabeth (NIH/NIAID) Higgs [E] (ehiggs@niaid.nih.gov) ehiggs@niaid.nih.gov); Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vvid3@cdc.gov; Gentles, Andrew (FDA/CDER) Andrew.Gentles@fda.hhs.gov; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov; Helen Schiltz (helen.schiltz@nih.gov) helen.schiltz@nih.gov); Hughes, Craig

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Subject: RE: Ebola MCM Scientific WG - Agenda (10/8)
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Subject. RE. Ebola MCM Scientific WG - Agerida (10/6)

Hello, everyone. I've attached a couple of documents for tomorrow's discussion.

For the first topic (manufacturing timelines), I've attached a brief deck summarizing the scheduled manufacturing of REGN-EB3 and mAb114 that is being supported by BARDA contracts. This was put together a couple of weeks ago obviously, but it is still an accurate summary of the current manufacturing schedule and the projected adds to the clinical supplies of REGN-EB3 and mAb114.

Second is a paper drafted by CDC that provides background and opens the discussion up for a potential recommendation that 16,000 1mL doses of the Merck vaccine be made available to Uganda, Rwanda and South Sudan. This discussion will be led by Rosalind Carter and Anita Samuel during the second half of tomorrow's meeting.

Thanks again and talk to you soon.

David

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Subject: Ebola MCM Scientific WG - Agenda (10/8)
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Good morning, everyone. I've attached the agenda for tomorrow's meeting. As you can see, we have a pretty aggressive schedule so I'll look to start promptly at 10:30am and I've double checked the access

code so we should be good on that front. I believe some slides might help the summary of the BARDAsupported manufacturing so I'll try to get a brief deck together and out to the group this evening.

On a housekeeping note, I believe I have everyone included and assigned correctly in the participant list. If there are any mistakes, please let me know. Also, if you're on this distribution list and do not plan to participate on a regular basis going forward, please let me know and I can update accordingly. Thanks!

David Boucher, PhD Chief. Antivirals & Antitoxins **Division of CBRN Countermeasures** Biomedical Advanced Research and Development Authority (BARDA) Office of Assistant Secretary for Preparedness and Response (ASPR) U.S. Department of Health & Human Services (HHS) 200 C St SW, 24L13 Washington DC 20024 Office: (202) 692-4619 Cell: (b)(6) david.boucher@hhs.gov



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Delivered Date: 2019/10/13 10:33:00

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Subject: RE: Ebola MCM WG Draft Meeting Summary

Date: 2019/11/12 17:26:00

Priority: Normal

Type: Note

Thought the group might find this interesting -

WHO prequalifies Ebola vaccine, paving the way for its use in high-risk countries

12 November 2019 - The World Health Organization (WHO) today prequalified an Ebola vaccine for the first time, a critical step that will help speed up its licensing, access and roll-out in countries most at risk of Ebola outbreaks. This is the fastest vaccine prequalification process ever conducted by WHO.

Prequalification means that the vaccine meets WHO standards for quality, safety and efficacy. United Nations agencies and Gavi, the Vaccine Alliance, can procure the vaccine for at-risk countries based on this WHO recommendation.

"This is a historic step towards ensuring the people who most need it are able to access this life-saving vaccine," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "Five years ago, we had no vaccine and no therapeutics for Ebola. With a prequalified vaccine and experimental therapeutics, Ebola is now preventable and treatable."

The injectable Ebola vaccine, Ervebo, is manufactured by Merck (known as MSD outside the US and Canada). It has been shown to be effective in protecting people from the Ebola Zaire virus and is recommended by the WHO Strategic Advisory Group of Experts (SAGE) for vaccines as part of a broader set of Ebola response tools. The decision is a step towards greater availability of the vaccine in the future, though licensed doses will only be available mid-2020.

This announcement comes less than 48 hours after the European Commission decision to grant a conditional marketing authorization for the vaccine, following the recommendation from the European Medicines Agency (EMA).

Due to the urgent public health need for a prequalified Ebola vaccine, WHO accelerated prequalification by reviewing safety and efficacy data as the information became available. Representatives from the prequalification team participated in the EMA evaluation process to address programmatic suitability for at-risk countries in Africa.

"The development, study, and rapid prequalification of this vaccine show what the global community can do when we prioritize the health needs of vulnerable people," said Dr Tedros.

WHO is also facilitating licensing of the vaccine for use in countries at risk of Ebola outbreaks, based on the reviews and positive outcome by the EMA. WHO, with the support of EMA, has worked closely with many African regulators who have indicated they will quickly license the vaccine following the WHO recommendation.

More information

WHO roadmap for introduction and roll out of a licensed Ebola vaccine:

https://www.who.int/medicines/news/2019/roadmap for intro roll out licensed ebola vaccine/en/

Press release, 18 October: Major milestone for WHO-supported Ebola vaccine

https://www.who.int/news-room/detail/18-10-2019-major-milestone-for-who-supported-ebola-vaccine

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Subject: Ebola MCM WG Draft Meeting Summary

Hello, everyone. I've attached a draft summary of today's meeting. Please send me any comments, questions or suggested edits by COB Wednesday. Thanks again!

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Subject: WHO commemorates the 40th anniversary of smallpox eradication

Date: 2019/12/13 09:22:00

Priority: Normal

Type: Note

FYI

https://www.who.int/news-room/detail/13-12-2019-who-commemorates-the-40th-anniversary-of-smallpox-eradication

Historic milestone underscores urgent need to invest in global health security and universal health coverage

13 December 2019 I News release I Geneva, Switzerland---The World Health Organization commemorated the 40th anniversary of smallpox eradication today recognizing the historic moment on 9 December 1979 when the end of smallpox was confirmed to have been eradicated. Five months later, in May 1980, the 33rd World Health Assembly issued its official declaration that 'the world and all its peoples have won freedom from smallpox'.

A bronze plaque marking the end of a scourge that had afflicted millions for thousands of years was unveiled at WHO headquarters in Geneva in the very same meeting room where, four decades earlier, the 19 members of the Global Commission for the Certification of Smallpox Eradication certified that smallpox had been eradicated from the world.

Speaking at the event attended by country representatives, UN representatives and WHO staff who worked on smallpox, WHO Director-General Tedros Adhanom Ghebreyesus said, "Today, smallpox is the only human disease ever eradicated, a testimony to what we can achieve when all nations work together.

When it comes to epidemic disease, we have a shared responsibility and a shared destiny. With this plaque, we commemorate the heroes around the world who came together to fight smallpox and worked to keep future generations safe. "

Until it was wiped out, smallpox had plagued humanity for at least 3000 years, killing 300 million people in the 20th century alone. The last known endemic case of smallpox was reported and the outbreak promptly contained in Somalia in 1977.

The successful smallpox eradication programme yielded vital knowledge and tools for the field of disease surveillance, the benefits of ring vaccination and the importance of health promotion in fighting

diseases such as poliomyelitis and the Ebola virus. It also laid the foundation for stronger national immunization programmes worldwide, underpinning the establishment of primary health care in many countries and creating momentum toward Universal Health Coverage.

Today's commemoration kicks off a year-long campaign in which WHO and partners will mark the eradication of smallpox and raise awareness about the need to continue the fight against polio and other diseases and accelerate investments in global health security. A smallpox eradication exhibition will be unveiled at the World Health Assembly in May 2020 and is expected to travel to other events, including the United Nations General Assembly in New York.

More information:

The Smallpox Eradication Programme - SEP (1966-1980) https://www.who.int/features/2010/smallpox/en/

Archives of the Smallpox Eradication Programme https://www.who.int/archives/fonds collections/bytitle/fonds 6/en/

More about smallpox

https://www.who.int/csr/disease/smallpox/en/

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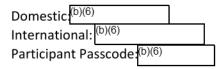
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Sent Date: 2019/12/13 09:22:47 **Delivered Date:** 2019/12/13 09:22:00

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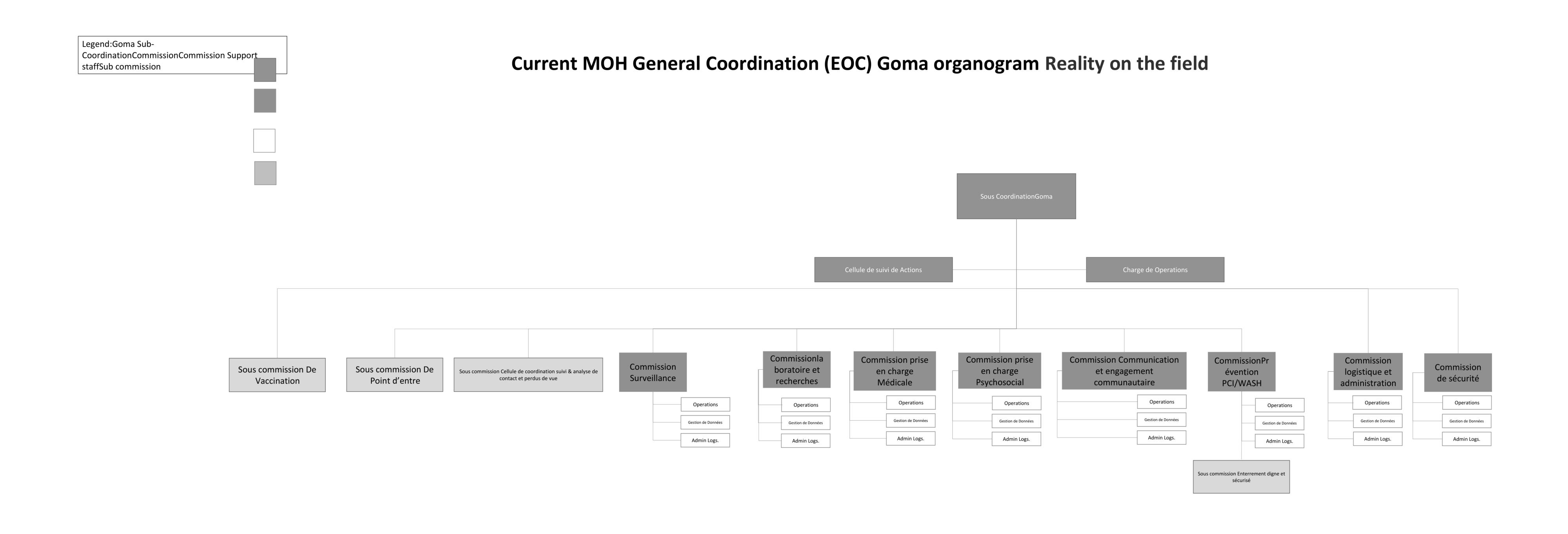
USG-WHO MCM Cooperation Call: Dr. Larry Kerr, Dr. Soumya Swaminathan and Dr. Bruce Aylward.



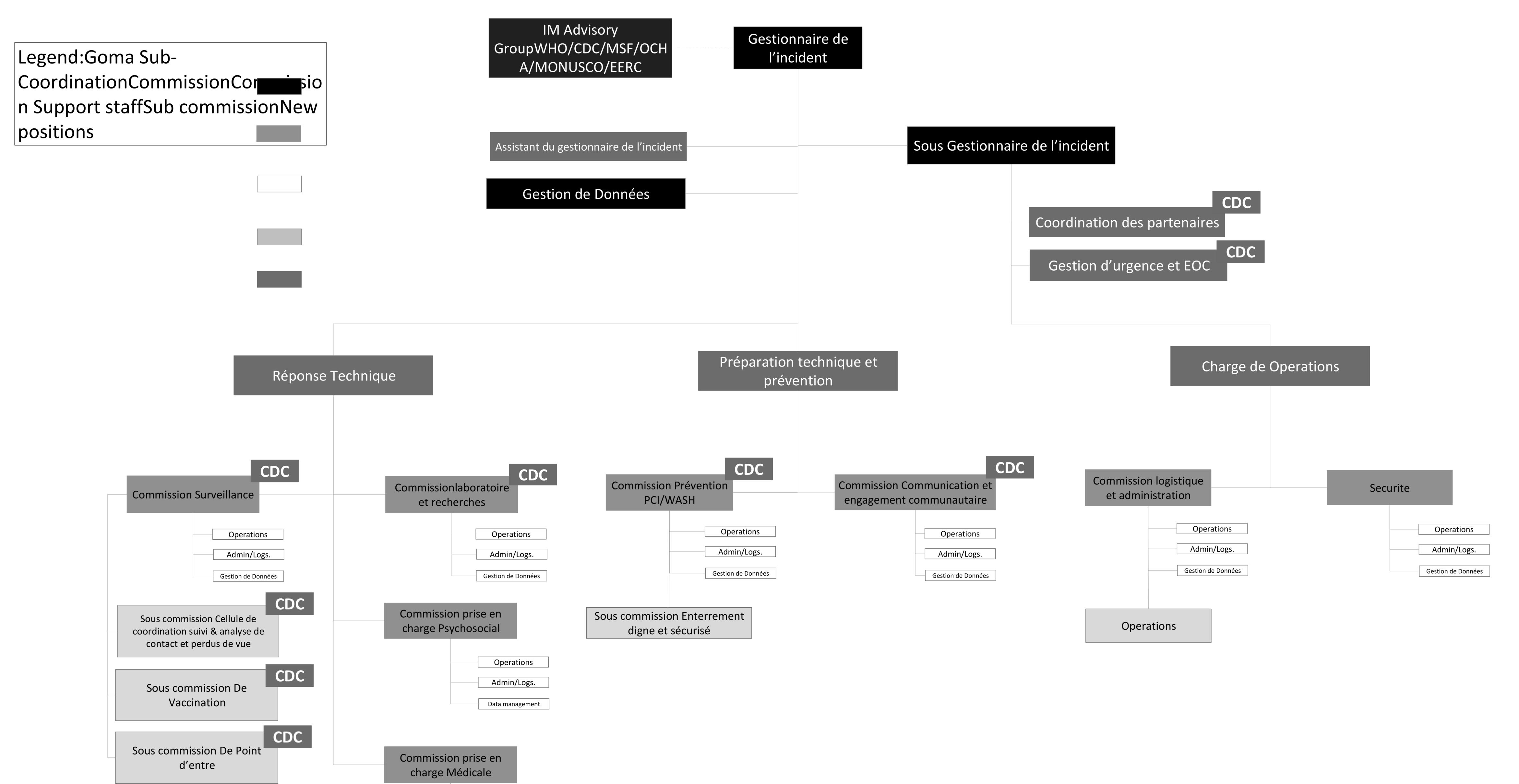
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Subject: RE: For review by 5 PM if possible: draft Sec. Azar and Sec. Pompeo op-ed

Date: 2020/02/04 14:55:34

Importance: High
Priority: Urgent
Type: Note

Couple of corrections and edits

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Sent: Tuesday, February 4, 2020 2:25 PM

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_	If possible, please let me know if you can clear this by 5 PM, so we can send it over to State.	_						
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Sent Date: 2020/02/04 14:55:33 **Delivered Date:** 2020/02/04 14:55:34 Page 202
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Page 203
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ESTIMATING THE NUMBER OF EBOLA CASES AND PROPORTION OF CASES IN EFFECTIVE ISOLATION, THE DEMOCRATIC REPUBLIC OF CONGO, 2018-2019

Ebola Case Projection Memo V3.19

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Background: On 1 August 2018, the Ministry of Health of the DRC declared a new outbreak of Ebola. As of 07 October 2019, 3,206 Ebola probable and confirmed cases have been reported by the WHO¹, of whom 2,143 (67%) have died. To prevent onward transmission and perpetuation of the outbreak, it is critical to identify cases early so that they may be effectively isolated², either by placement in an Ebola Treatment Unit and/or through effective vaccination of their contacts and contacts-of-contacts, so as to prevent onward transmission. Additionally, early treatment likely increases the chance of survival.

Questions/Objectives:

- a. What is the effectiveness of current intervention efforts, measured as the proportion of identified cases that are currently being identified and effectively isolated, either by placement in an Ebola Treatment Unit and/or by effective vaccination of their contacts and contacts-of-contacts, so as to prevent onward transmission?
- b. What is the potential impact of a hypothetical increase in cases effectively isolated on the likelihood of onward transmission?

Date: 9 October 2019

Authors: Centers for Disease Control and Prevention (CDC): Bishwa Adhikari, Brad Greening, Seonghye Jeon, Emily Kahn, Gloria Kang, Gabrielle Miller, Martin Meltzer, Health Economics and Modeling Unit (HEMU/DPEI); James Fuller (CGH/DGHP)

¹ WHO Ebola Health update – DRC 2019 – Ebola daily case numbers – 07 October 2019 (https://www.who.int/emergencies/diseases/ebola/drc-2019/)

² Effective isolation means preventing onward transmission of Ebola by ensuring that a patient is either physically isolated and / or their contacts are protected from infection. In addition, effective isolation can include minimizing the number of treatment facilities per case; vaccination of health care workers, frontline workers and community members, as well as Safe and Dignified Burials when needed.

RED FLAG ALERT: Based on the most recent data provided, we currently estimate that 65% of cases are effectively isolated, an increase from the 58% estimated in the previous memo. In addition, we have revised for August the estimates of the proportion of cases effectively isolated upwards from 58% to 59%. Assuming no changes, the epidemic is now projected to end by 5 May 2020 with 3,410 total cases. Other outbreak indicators have shown small levels of improvement (Table 2). Given the unknown degree of under-reporting of cases, however, these estimates of improvements should be interpreted with caution. To bring the outbreak to an end, the proportion of cases in effective isolation (ideally within 3 days of symptom onset) will need to reach (and be sustained at) approximately 70%.

BOTTOM LINE SUMMARY/SUMMARY OF RESULTS

BASE ANALYSIS

- Percent not effectively isolated: Based on 3,207 total cases reported up to 8 October 2019, approximately 35% of cases are not being effectively identified and isolated (i.e., 65% are effectively isolated) to prevent transmission of illness to others (see Table 1).
- Projected number of cases: Assuming that the proportion of Ebola cases not effectively isolated <u>remains</u> unchanged at 35% (Table 1), there will be an estimated cumulative total of 3,407 reported cases by 24 March 2020 (Figure 1a).
- Projections indicate that if the proportion of cases not effectively isolated remains at 35% (i.e., 65% effectively isolated), the number of new cases each week will decline slowly from now (early October 2019) through the end of March 2020, at which time there will be approximately 1 new case each week (Figure 1b). Assuming no changes, the epidemic would then end by 5 May 2020 with 3,410 total cases.

SENSITIVITY ANALYSIS

- The projected number of future cases is sensitive to the proportion of cases that are effectively isolated.
 - If the proportion of cases that are being effectively isolated is decreased from 65% to 55% (i.e., 45% not effectively isolated), by 24 March 2020 there will be an estimated cumulative total of 3,621 Ebola cases, with 8 new cases per week (Figure 1b). In this scenario, the outbreak continues beyond September 2020.
 - If the proportion of cases that are effectively isolated is raised from 65% to 75% (i.e., 25% not effectively isolated), the outbreak effectively ends by 4 February 2020 with a total of 3,329 total
- Illustration: If the proportion of cases effectively isolated gradually improves: An illustration of the potential impact of improved effectiveness of interventions was constructed by assuming the following: The proportion of Ebola cases effectively isolated is set at 65% (i.e., 35% not effectively isolated, Table 1) through 26 September 2019 and remains at 65% effectively isolated (35% not) during 27 September 26 October 2019. Then, 70% of cases are effectively isolated (30% not) from 27 October 25 December 2019; and 95% of cases are effectively isolated (5% not) from 26 December 2019 onward. Under those assumptions, the outbreak will end by 18 January 2020 (i.e., isolation of last case) with an estimated cumulative case count of 3,376 cases (Figure 1a).

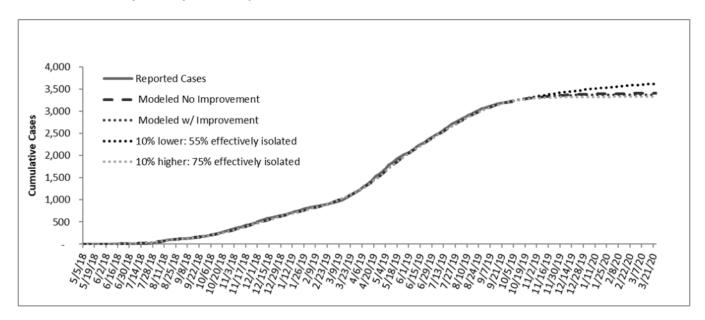
MAIN TABLES AND FIGURES

Table 1. The estimated proportion of Ebola cases that are not effectively isolated, January 2019 - present^{1†}

Outbreak Days	Dates	Proportion of cases <u>not</u> effectively isolated
241-270	31 Dec 2018 – 29 Jan 2019	50%
271-300	30 Jan – 28 Feb 2019	62%
301-330	1 Mar – 30 Mar 2019	67%
331-360	31 Mar – 29 Apr 2019	60%
361-390	30 Apr – 29 May 2019	43%
391-420	30 May – 28 June 2019	50%
421-450	29 June – 28 July 2019	48%
451-480	29 July – 27 Aug 2019	41%
481-510	28 Aug – 26 Sep 2019	35%
Estin	nating cases forward assuming NO	O change in percent cases <u>not</u> effectively isolated
511-690*	27 Sep 2019 – 24 Mar 2020	35%
Estim	ating cases forward assuming DE	CREASES in percent cases <u>not</u> effectively isolated
511-540	27 Sep – 26 Oct 2019	35%
541-570	27 Oct – 25 Nov 2019	30%
571-600	26 Nov – 25 Dec 2019	30%
601-690	26 Dec 2019 – 24 Mar 2020	5%

These estimates were produced by fitting modeled data to reported case counts as described in methods below and in Appendix 1.

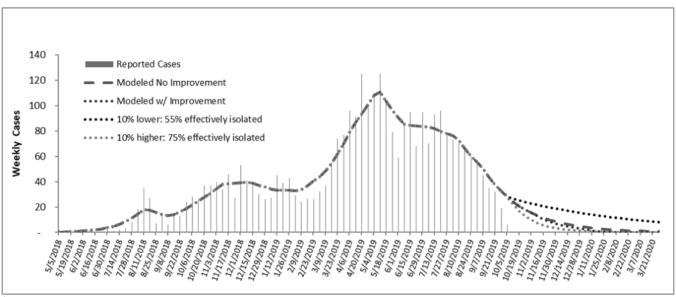
Figure 1a. Projected <u>cumulative</u> number of Ebola cases through 21 March 2020, with* and without** improvements in the proportion of cases effectively isolated (based on case reports as of 8 October 2019), base and sensitivity*** analysis – all reported cases¹¹



[†]The proportion of cases not effectively isolated for earlier time periods are listed in Appendix Table A4.1.

^{*}This assumes that no changes in the proportion of Ebola cases effectively isolated occurs after the date through which data have been provided.

Figure 1b. Projected <u>weekly</u> number of Ebola cases through 21 March 2020, with* and without** improvements in the proportion of cases effectively isolated (based on case reports as of 8 October 2019), base and sensitivity*** analysis – all reported cases¹¹



*The estimates of the scenario "Modeled with Improvement" were calculated assuming that there will be incremental improvements in effective isolation such that: 65% of cases are effectively isolated from 28 August – 26 October 2019; 70% of cases are effectively isolated from 27 October – 25 December 2019; and 95% of cases are effectively isolated from 26 December 2019 onward (see Table 1).

¶For some cases, we imputed date of symptom onset. See Methods section for details.

IMPORTANT CAVEATS

All case estimates and projections presented are based on reported case data provided by WHO on 8 October 2019, unless otherwise stated.

- a) The accuracy of case estimates and projections depends on the accuracy of case reports.
- The estimates and projections may change as more data are reported.
- c) Projections made for future dates become more uncertain the farther out we project, as it is unknown how conditions may change over time. The projections provided assume that the present trends and conditions remain unchanged into the future and should be interpreted as providing relative comparisons between intervention strategies (given all caveats and assumptions listed). The estimates should not be considered exact predictions of the future.

^{**}The estimates of future cases were produced by assuming that 35% of identified cases are only being isolated after they have infected other people and caused onward transmission (Table 1).

^{***}Sensitivity analyses demonstrate the projected number of Ebola cases if the modeled estimate of cases effectively isolated is +/ - 10% than the base analysis (Table 1) beginning 27 September 2019.

EXPANDED RESULTS

Other epidemiologic indicators (Table 2) help evaluate the estimates presented here and assess the overall success of current response efforts. For example, during the past 3 weeks (from 18 September to 08 October), 20% of all new Ebola cases were only identified as Ebola cases at or after the time of death (i.e., community deaths), and 28% of new cases were not previously identified as contacts of other cases. Furthermore, only 39% of new cases were isolated early in the course of disease, i.e., within 3 days of symptom onset.

Table 2: Additional outbreak indicators: Characteristics of new confirmed cases (n=59) for 18 September – 08 October 2019

Characteristic	Cases	%	Target %*
Community Deaths [†]	12	20%	0%
Not Known Contacts	16	28%	20%
Cases isolated within 3 days of symptom onset	22	39%	70%
Known and Monitored Contacts	29	50%	80%
Health Care Worker Infections	2	3%	0%

*Cases identified at time of death. The high proportion of community deaths reported among confirmed cases, persistent delays in detection and isolation in ETUs, and challenges in the timely reporting and response to probable cases all collectively increase the likelihood of further chains of transmission in affected communities and contribute to increased risk of geographical spread within the Democratic Republic of the Congo and to neighboring countries. (CDC/CGH/DGHP Communication, 14 August 2019)

*Targets are based on the assumption that in order to rapidly end the outbreak approximately 70% of cases must be effectively isolated. (1) This was shown to be a realistic policy goal in the 2014-16 West African Ebola outbreak. (12)

ACCURACY

To track the accuracy of model estimates, we have been comparing the projected cases counts to the reported cases counts for 14 days, 28 days and 42 days from the date of the initial model run (Appendix Table A2.1). Since 30 January 2019, when we began imputing dates of symptom onset, modeled projections have been accurate to approximately 5% for the 14-day projections and around 10% for the 28-day projections on average (Appendix Table A2.1). Most projections have been under-estimated (i.e., actual cases recorded at a future date have been greater than those estimated from the model when the memo was produced). Some memos, however, included over-estimates of future cases (i.e., model results were greater than the resulting number of actual cases) (Appendix Figure A2.1); this may be due to an approximate 25% of cases not being reported during late May – early June 2019 (10,11). Since memo version 3.10 (produced 5 June 2019), model accuracy has notably improved, with projected estimates falling within 10% of actual case counts as far out as 12 weeks into the future. (Appendix: Table A2.1, Figure A2.1).

SENSITIVITY ANALYSIS

We conducted a sensitivity analysis to show the impact of ±10% difference in the percentage of cases that are effectively isolated on projections of future case counts (Figures 1a and 1b). In the base analysis, we estimate that 65% of cases are being effectively isolated from 28 August 2019 onward, resulting in an estimated 3,407 Ebola cases by 24 March 2020. If the estimated proportion of cases that are effectively isolated is lowered to 55% beginning 27 September 2019, there would be an estimated 3,621 Ebola cases by 24 March 2020 with 8 new cases per week; in this scenario, the outbreak would be expected to continue beyond September 2020. If the estimated proportion of cases that are effectively isolated is raised to 75% beginning 27 September 2019, the outbreak would be expected to effectively end as of 4 February 2020 with a total of 3,329 cases.

METHODS

We used the EbolaResponse model (available at http://dx.doi.org/10.15620/cdc.24900) to determine the proportion of Ebola cases in two categories:

- 1. Patients effectively isolated (i.e., either by placement in an Ebola Treatment Unit and/ or their contacts and contacts-of-contacts are effectively vaccinated, so as to prevent onward transmission), such that there is a reduced risk of disease transmission
- 2. Patients not effectively isolated, such that there is continued risk of onward transmission.

Estimates of the proportions of cases in these categories were produced by fitting the modeled data to the actual confirmed/probable cumulative case counts from DRC (Appendix 1: Figure A1.2) provided by the Goma Analytic Cell, which reports to the DRC Ministry of Health's Emergency Operations Center.

Imputation of date of symptom onset for cases missing data

Cases without reported date of symptom onset were assigned a date of symptom onset that was 7 days earlier than their case report dates. Of the 3,207 cases (3,093 confirmed + 114 probable) included in the analyses reported in this memo, 183 (6%) cases were missing date of symptom onset; for these cases we used the imputed date of symptom onset.

Additional description of Methods:

A detailed description of the methods and assumptions used in the EbolaResponse model is provided in Appendix 1.

LIMITATIONS

- The modeled data presented here project case counts through 24 March 2020. Estimates of future cases <u>become</u>
 more uncertain the farther out we project, as it is unknown how conditions may change over time. The projections
 provided assume that the present trends and conditions remain unchanged into the future and should be
 interpreted as providing the estimated impact of intervention vs. no intervention strategies.
- The EbolaResponse model uses 30-day increments to model changes in the proportion of Ebola cases assigned to each category.
- The main set of results presented in this memo do not take into account any corrections for underreporting. The World Health Organization has estimated that up to 25% of cases may not be recorded/reported (10, 11). There are no data on how such underreporting may have changed over the course of the epidemic to date.

APPENDIX 1: EbolaResponse tool: Methods and Assumptions

Model overview:

We built a spreadsheet-based model, called EbolaResponse, that allows a user to estimate the number of Ebola cases in the DRC and the proportion of cases that are effectively isolated such that onward Ebola transmission is prevented (1).

Type of model:

Our model, EbolaResponse, tracks patients through the following states: Susceptible (not yet infected); infected people incubating Ebola virus (but not yet infectious), infectious, recovered or dead (an SIIR model). The model is in effect, a Markov Chain model, and is similar in concept to that built by Chowell et al. (2). The one exception is that Chowell et al. included a state labeled "Exposure" and did not include our "incubating but not infectious category".

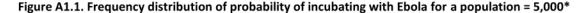
We use probabilities, drawn from reports of Ebola outbreaks, to model the daily movement of patients between and within the states. For example, for duration of incubation period, we adapted data from (3), which indicates the probability (likelihood) that patients will incubate 1, 2, 3 or more days, up to a maximum of 25 days (see below).

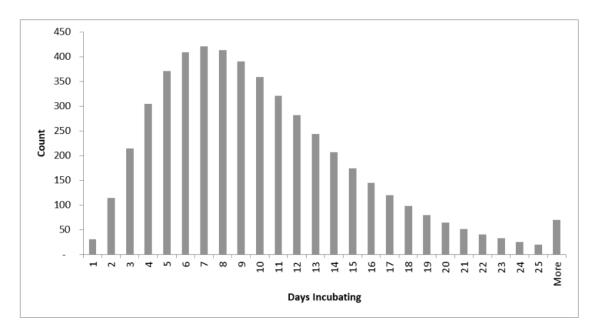
Progression only: A patient can only progress forward through the model, and can never regress (e.g., can never go from incubating back to susceptible). Nor can a patient skip a state (e.g., go from incubating to recovered, skipping infectious).

Community size: We used a community size of 78.7 million people (the estimated 2016 national population of the DRC, (3). The community size can be readily altered in the model.

Incubation period: We adapted published *probability distribution* data (3) to construct a gamma probability distribution of incubating with Ebola (Figure A1.1 and Table A1.1). We use a mean incubation period of 10.02 days (3).

Previous data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda (2), estimated mean incubation periods of 5.30 (SD 0.23) and 3.35 (SD 0.49) days, respectively. These appear to be lower than other published estimates (5, 6). Some of the differences may be attributable to different sub-types of the virus (5). Within the EbolaResponse model, the probability distribution for incubation can be readily changed to almost any structure desired, with an upper limit of 25 days incubation.





^{*} Source: Adapted from (3).

Table A1.1: Frequency distribution of probability of incubating with Ebola

Days	Frequency	Percent	Cumulative Percent	Days	Frequency	Percent	Cumulative Percent
1	31	0.6%	0.2%	14	207	4.1%	79.6%
2	114	2.3%	1.6%	15	174	3.5%	83.4%
3	215	4.3%	4.9%	16	145	2.9%	86.6%
4	305	6.1%	10.1%	17	120	2.4%	89.2%
5	371	7.4%	16.9%	18	98	2.0%	91.4%
6	409	8.2%	24.7%	19	79	1.6%	93.2%
7	421	8.4%	33.1%	20	64	1.3%	94.6%
8	413	8.3%	41.5%	21	51	1.0%	95.7%
9	391	7.8%	49.5%	22	60	1.2%	96.7%
10	358	7.2%	57.0%	23	50	1.0%	97.4%
11	321	6.4%	63.8%	24	45	0.9%	98.0%
12	282	5.6%	69.8%	25	35	0.7%	98.4%
13	243	4.9%	75.1%				
				Totals	5,000	100.0%	

Source: Adapted from (3).

Infectious period:

Based on WHO data, we used an infectious period of 6 days (3). This would include any time taken for a traditional burial. Chowell et al, using data from a 1995 outbreak in the Democratic Republic of the Congo (formerly Zaire) and a 2000 outbreak in Uganda, estimated mean infectious periods of 5.6 and 3.35 days, respectively (2). This period of 6 days includes all stages of symptomatic illness. It is true that patients may be symptomatic for longer periods (see 3) but being symptomatic is different than having the risk of onward transmission.

Note that the risk of onward transmission, absent effective isolation, does change as a patient becomes sicker (7, 8). However, EbolaResponse does not track individual patients. Instead, the model employs aggregate (e.g., mean) risk of onward transmission, aggregated over the entire period of symptomatic illness (1).

Potential risk: The following description from northern Uganda indicates the potential risk, due to possible contact with a victim's body fluids, posed by traditional burial of an Ebola victim: "A brief study indicated that once a person died, his or her paternal aunt (father's sister) was called to wash and prepare the body for burial. If the father did not have a sister, an older woman in the victim's patriline was asked to prepare the body. Generally, the woman removed the clothes from the body, washed the body, and dressed the deceased in a favorite outfit. At the funeral, all family members ritually washed their hands in a common bowl, and during open casket all were welcome to come up to deceased person and give a final touch on the face or elsewhere (called a love touch). The body was then wrapped in a white cloth or sheet and buried." (9)

Population "governor"

Although we explicitly don't include an "exposed" population element in the model, we do include a population "governor" that prevents the model from calculating more cases than the inputted population. This "over-calculation" could happen if one assumes that there is a relatively large percentage (defined below) of the population that become infected and are not effectively isolated, presenting a risk of onward disease transmission (Table A1.3).

We programmed the governor by simply reducing the daily estimate of the persons newly infected proportionate to the cumulative reduction in the susceptible population, as follows:

Factor to reduce estimate of newly infected at Day t = (Model population – cumulative total of newly infected up to day (t-1)/ model population.

What this "governor" essentially does is to reduce, on a daily basis, the effective number of persons infected (i.e., effectively lowers the risk of transmission inputs shown in Table A1.3). In most instances, with "large populations," this

governor is unlikely to impact the calculations. The "governor" only begins to appreciably impact estimates (i.e., reduce them) when approximately 40% - 50% of the population have become infected.

Population and numbers initially infected
Country: The Democratic Republic of the Congo

Total Population: 78.7 million Number Initially Infected: 1

Distribution of patient by category over time

As explained in the main text, we split the patients into two categories of isolation, as follows:

- 1. Patients effectively isolated (i.e., hospitalized in ETCs or otherwise receiving medical care), such that there was reduced contact with others and a reduced risk of disease transmission.
- 2. Patients not effectively isolated, such that there was continued risk of onward transmission.

We explain how we calculate the percentage of patients in each category in the "goodness-of-fit" sub-section (below).

The risk of onward transmission from an Ebola patient to susceptible persons, by patient category, is shown in Table A1.3.

The distribution of patients into these categories affects the overall progress of the epidemic. The more patients in the "effectively isolated" category, the slower the progress of the epidemic because this category has a transmission rate of less than 1 person infected per infectious person. The distribution of patients into these categories, and how we changed those distributions over time, is shown in Table 1.

Table A1.3: Risk of onward transmission by category of patient: Values fitted to data compared to those in the literature

Patient category		Daily risk of onward tra	Total numbers infected per infectious person**			
	Values fro	om literature (95% CI)†	Values used to fit	Value	Model	
			to data in DRC*	literatur	e (95% CI)	estimates
Effectively	DRC	0.1134	0.03	DRC	0.4	0.18
isolated		(0.00001 - 0.5842)			(0 - 2.2)	_
	Uganda	0.0017		Uganda	0.01	
		(0.0 - 0.918)			(0 - 3.5)	
No effective	DRC	1.0932	0.3	DRC	1.8	1.8
isolation	solation (0.00001 – 1.42				(0 - 2.3)	_
	Uganda	0.066	•	Uganda	0.1	
		(0.0 - 3.0367)			(0 - 3.2)	

^{*} These are the values used in the model in order to obtain a "good fit" to the data-to-date.

Source; Adapted from Legrand et al., 2007 (6).

Goodness-of-Fit:

Scenarios: Fitting to the existing data

For the original conception of the model, we essentially "reverse engineered" the following variables:

- i) Percentage of patients in each of the categories (effectively isolated; No effective isolation), with percentages changing over time (increments of 30 days) (see Main Text, Table 1).
- ii) Risk of transmission by type of patient, with daily risk of onward transmission changing over time (increments of 30 days) (see Appendix Table A1.3).

^{**} Values of "Total number of persons infected per infectious person": When these values remain below 1 person infected per infectious person, then the epidemic will eventually end. For model: These are the equivalent values used to fit the model to the data, assuming 6 days of infectiousness (e.g., $0.3 \times 6 = 1.8$ persons infected per infectious person as per model fit)

[†] Values adapted from weekly values given by Legrand et al (6), from Ebola outbreaks in 1995 in Democratic Republic of Congo (DRC) (formerly Zaire), 2000 in Uganda. CI = Confidences Intervals.

^{††} We used, as proxies for "effective isolation," Legrand et al.'s measurements of "community component" (without burial) from DRC, as these were below 1.

For the purpose of this analysis, we held fixed the previously used values for risk of transmission and only varied the percentage of patients in each of the three categories. Essentially, we "balance" the percentages in "effectively isolated" and "NOT effectively isolated" until the plot of the model "fits" the plot of the actual data, as shown in Figure A1.2. Figure A1.2 shows the goodness-of-fit, comparing estimates of cases produced using EbolaResponse model to reported confirmed and probable Ebola cases.

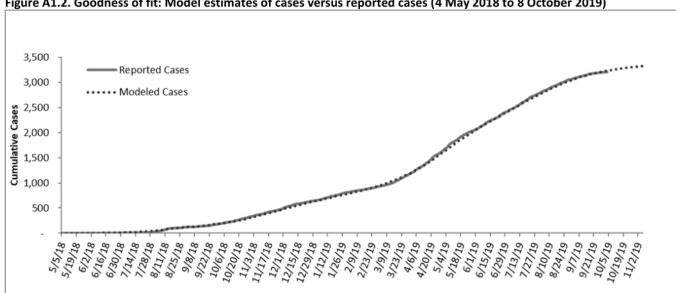
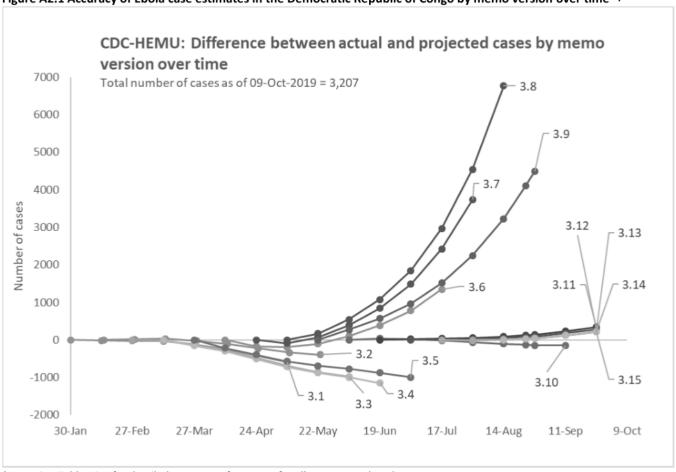


Figure A1.2. Goodness of fit: Model estimates of cases versus reported cases (4 May 2018 to 8 October 2019)

APPENDIX 2: Accuracy of Model Estimates

Figure A2.1 Accuracy of Ebola case estimates in the Democratic Republic of Congo by memo version over time*†



^{*}Note: See Table A2.1 for detailed summary of accuracy for all memos produced.

[†] The graph shows plots of accuracy, in 2-week segments, of selected memo versions of previous memos indicated by the version number. The y-axis represents count differences between modeled future cases and actual case counts on a given date. For example, the plot of memo version 3.7 (produced 24 April 2019), shows that those estimates of cases expected by 8 May 2019 differed by about 88 cases (5%) below the actual number of cases that occurred on that date. By 19 June 2019, the estimates produced on 24 April 2019 were approximately 37% greater (N = 847 cases) than actually reported. This decrease in accuracy is attributed to the temporary decline in reported cases in late May – which may be due to an approximate 25% of cases not being reported during that period. (10, 11)

Figure A2.2 Boxplot of accuracy of Ebola case estimates in the Democratic Republic of Congo

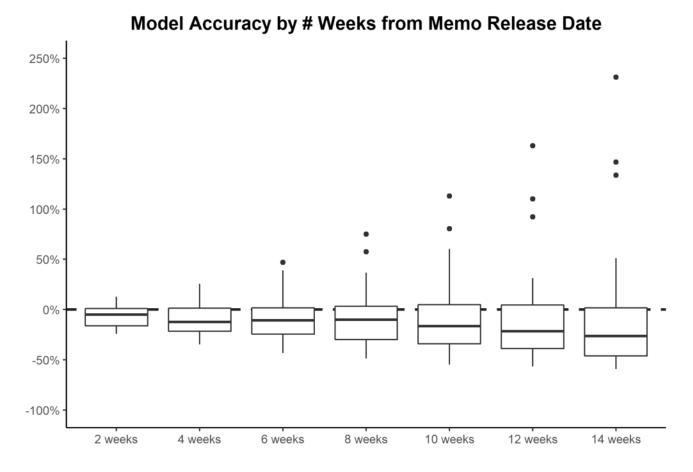


Figure A2.2 is a box-plot of accuracy of all the results reported in the memos (Figure A2.1), regardless of the date of when the estimate was made. The plot is given in standard Tukey format, where the boxes plot the range of the middle 50% of all estimates (Quartile 1 – Quartile 3). The box is split by a line indicating the median. The 'whiskers' extend to the farthest point that are not considered outliers, where an outlier is shown by a dot, and is defined as being >1.5x the interquartile range (Quartile 1 – Quartile 3) from the end of the box.

Interpretation: The majority of the memos have under-estimated reported cases by less than 50% (i.e., the boxes are between 0% and -50%). A small percentage (less than 10%) of estimates over-estimated by more than 100% (the top of the "whiskers' at 10, 12 and 14 weeks), however, all such estimates are considered outliers according to the definition given above.

Table A2.1. Accuracy of Ebola case estimates in Democratic Republic of Congo, 2-, 4-, and 6-weeks post-estimate*^

				14-day (2 weeks)			28-day (4 weeks)			42-day (6 weeks)					
Memo Version and		Data date ar	ata date and total			Cases			Cases			Cases			
Date		reported cases		Date	Actual	Estimated	% diff	Date	Actual	Estimated	% diff	Date	Actual	Estimated	% diff
1.1	11-Oct-18	5-Oct-18	179	19-Oct-18	260	199	-23%	2-Nov-18	330	216	-35%	16-Nov-18	410	232	-43%
2.0	18-Oct-18	16-Oct-18	214	30-Oct-18	317	240	-24%	13-Nov-18	386	268	-31%	27-Nov-18	462	297	-36%
2.1	23-Oct-18	23-Oct-18	238	6-Nov-18	347	289	-17%	20-Nov-18	424	329	-22%	4-Dec-18	504	368	-27%
2.2	6-Nov-18	5-Nov-18	305	19-Nov-18	422	352	-17%	3-Dec-18	500	398	-20%	17-Dec-18	580	443	-24%
2.3	14-Nov-18	14-Nov-18	339	28-Nov-18	467	411	-12%	12-Dec-18	554	475	-14%	26-Dec-18	618	544	-12%
2.4	21-Nov-18	21-Nov-18	373	5-Dec-18	513	442	-14%	19-Dec-18	589	509	-14%	2-Jan-19	650	580	-11%
2.5	6-Dec-18	4-Dec-18	458	20-Dec-18	596	504	-15%	3-Jan-19	653	550	-16%	17-Jan-19	723	591	-18%
2.6	19-Dec-18	17-Dec-18	542	2-Jan-19	<i>650</i>	<i>570</i>	-12%	16-Jan-19	721	623	-14%	30-Jan-19	799	674	-16%
2.7	2-Jan-19	2-Jan-19	598	16-Jan-19	721	593	-18%	30-Jan-19	799	623	-22%	13-Feb-19	859	648	-25%
2.8	15-Jan-19	15-Jan-19	648	29-Jan-19	797	630	-21%	12-Feb-19	857	658	-23%	26-Feb-19	914	681	-25%
V 3.1	30-Jan-19	30-Jan-19	733	13-Feb-19	859	837	-3%	27-Feb-19	924	900	-3%	13-Mar-19	997	962	-4%
V 3.2	14-Feb-19	14-Feb-19	820	28-Feb-19	931	948	2%	14-Mar-19	1006	1037	3%	28-Mar-19	1161	1132	-2%
V 3.3	27-Feb-19	27-Feb-19	871	13-Mar-19	997	947	-5%	27-Mar-19	1147	988	-14%	10-Apr-19	1325	1022	-23%
V 3.4	13-Mar-19	13-Mar-19	920	27-Mar-19	1147	988	-14%	10-Apr-19	1325	1022	-23%	24-Apr-19	1559	1052	-33%
V 3.5	27-Mar-19	27-Mar-19	1,020	10-Apr-19	1325	1103	-17 %	24-Apr-19	1559	1165	-25%	8-May-19	1796	1226	-32%
V 3.6	10-Apr-19	10-Apr-19	1,177	24-Apr-19	1559	1390	-11%	8-May-19	1796	1601	-11%	22-May-19	1978	1870	-5%
V 3.7	24-Apr-19	24-Apr-19	1,360	8-May-19	1796	1705	-5%	22-May-19	1978	2049	4%	5-Jun-19	2118	2510	19%
V 3.8	8-May-19	8-May-19	1,591	22-May-19	1978	2144	8%	5-Jun-19	2118	2660	26%	19-Jun-19	2284	3360	47 %
V 3.9	22-May-19	20-May-19	1,857	5-Jun-19	2118	2391	13%	19-Jun-19	2284	2851	25%	3-Jul-19	2463	3425	39%
V 3.10	5-Jun-19	5-Jun-19	2,016	19-Jun-19	2284	2324	2%	3-Jul-19	2463	2475	0%	17-Jul-19	2628	2607	-1%
V 3.11	19-Jun-19	19-Jun-19	2,181	3-Jul-19	2463	2486	1%	17-Jul-19	2628	2665	1%	31-Jul-19	2792	2842	2%
V 3.12	3-Jul-19	3-Jul-19	2,372	17-Jul-19	2628	2636	0%	31-Jul-19	2792	2806	1%	14-Aug-19	2930	2975	2%
V 3.13	17-Jul-19	17-Jul-19	2,515	31-Jul-19	2792	2771	-1%	14-Aug-19	2930	2933	0%	28-Aug-19	3057	3093	1%
V 3.14	31-Jul-19	31-Jul-19	2,690	14-Aug-19	2930	2933	0%	28-Aug-19	3057	3093	1%	11-Sep-19	3135	3252	4%
V 3.15	14-Aug-19	14-Aug-19	2,843	28-Aug-19	3057	3093	1%	11-Sep-19	3135	3252	4%	25-Sep-19	3193	3409	7%
V 3.16	28-Aug-19	28-Aug-19	2,997	11-Sep-19	3135	3241	3%	25-Sep-19	3193	3389	6%	9-Oct-19	-	3534	-
V 3.17	11-Sep-19	11-Sep-19	3,091	25-Sep-19	3193	3284	3%	9-Oct-19	-	3391	-	23-Oct-19	-	3490	-
V 3.18	25-Sep-19	24-Sep-19	3,175	9-Oct-19	-	3302	-	23-Oct-19	-	3368	-	6-Nov-19	-	3425	-
V 3.19	9-Oct-19	8-Oct-19	3,207	23-Oct-19	-	3293	-	6-Nov-19	-	3323	-	20-Nov-19	-	3346	-

^{*}Actual case counts taken from CDC line list data; includes all confirmed and probable cases. ^ Models (from version 3.1 onward) were run using cases with imputed date-of-symptom onset. Including those with imputed date-of-symptom onset improves the model fit. The number of cases with imputed date-of-symptom onset is provided in the Methods section of the main text. Case count data from WHO line listing starting from version 3.16 (28-Aug-19).

APPENDIX 3: Log of recent changes to previous memo versions

(Full log of all changes to each previous memo version and changes in estimates over time are available upon request to: eocmodelingunit@cdc.gov)

Changes from V3.18 to 3.19

- Updated model fit with case report data provided by WHO in coordination with CDC IMS Ebola Response Epi-Lab Task Force available through 8 October 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming
 the following changed scenario for future changes in the proportion of cases effectively isolated such that onward
 transmission is prevented:
 - 59% of cases from 29 July 27 August 2019
 - 65% of cases from 28 August 26 September 2019
 - o 65% of cases from 27 September 26 October 2019
 - o 70% of cases from 27 October 25 November 2019
 - o 70% of cases from 26 November 25 December 2019
 - o 95% of cases from 26 December 2019 24 March 2020

Changes from V3.17 to 3.18

- Updated model fit with case report data provided by WHO in coordination with CDC IMS Ebola Response Epi-Lab Task Force available through 24 September 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming
 the following changed scenario for future changes in the proportion of cases effectively isolated such that onward
 transmission is prevented:
 - 52% of cases from 29 June 28 July 2019
 - o 58% of cases from 29 July 27 August 2019
 - 58% of cases from 28 August 26 September 2019
 - 58% of cases from 27 September 26 October 2019
 - o 64% of cases from 27 October 25 November 2019
 - 70% of cases from 26 November 25 December 2019
 - 95% of cases from 26 December 2019 23 February 2020

Changes from V3.16 to 3.17

- Updated model fit with case report data provided by WHO in coordination with James Fuller (CGH/DGHP) available through 10 September 2019.
- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming the following changed scenario for future changes in the proportion of cases effectively isolated such that onward transmission is prevented:
 - 52% of cases from 29 June 28 July 2019
 - 54% of cases from 29 July 27 August 2019
 - o 54% of cases from 28 August 26 September 2019
 - 54% of cases from 27 September 26 October 2019
 - 62% of cases from 27 October 25 November 2019*
 - 70% of cases from 26 November 25 December 2019
 - o 95% of cases from 26 December 2019 23 February 2020
 - *Note: Schedule for improvement in interventions schedule changed to start on 27 October 2019.
- Removed the sensitivity analysis scenario of a 20% improvement to the current/base analysis.

Changes from V3.15 to 3.16

- The source of data used to update model fit was changed from the CDC dataset to the WHO dataset. The data from these sources was very similar and this change had a negligible impact on model fitness and results.
- Updated model fit with case report data provided by WHO in coordination with James Fuller (CGH/DGHP) available through 27 August 2019.

- Estimated the projected case counts and impact of improving the proportion of Ebola cases effectively isolated assuming the following changed scenario for future changes in the proportion of cases effectively isolated such that onward transmission is prevented:
 - o 51% of cases from 29 July 27 August 2019
 - o 51% of cases from 28 August 26 September 2019
 - o 60% of cases from 27 September 26 October 2019*
 - o 70% of cases from 27 October 25 November 2019
 - o 95% of cases from 26 November 2019 23 February 2020

*Note: Schedule for improvement in interventions schedule changed to start on 27 September 2019.

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Dear All

A recent paper suggests the outbreak is caused by two viruses with different aggressiveness. We like to point out that this analysis did not describe any new viruses. It analyzed virus genomes that are constantly being shared with the global scientific community via the GISAID platform, thanks to the great efforts from many labs initially in China and now also around the world. Viruses do keep changing naturally and form groups of genetically related viruses depending where and when they circulate.

The difference between these groups is minimal and rarely linked to changes in severity for which there is no hard evidence presented in that paper. The differences between the virus genetic groups in the case of this virus can be likened with comparing two cars of identical type and color just with a different license plate. That license plate helps you finding out where the car was registered but not how fast it can go. A lot more data is needed for the latter.

Assigning viruses to these genetic groups can be useful in determining patterns of transmission and global circulation as well as effects of human intervention. In this case, the analysis shows indeed decline of the variant dominant in Wuhan and Hubei Province which could be explained by the good effort of human intervention by the Chinese government among other factors. This has shown that the virus can be brought down. More data will be needed to fill gaps in the early history of this virus.

The recent paper in question, used 103 virus genomes while today there are far more known virus genomes on GISAID and that number is growing daily. Through that, we are seeing several more versions or "license plates" than just the two discussed in the paper, all within the expected natural variation behavior of a virus like this. In order to better describe this and facilitate discussion on clades we have added clade names based on marker mutations accordingly and also show detailed trees of major subclades.

Some observations:

- S clade: new USA-WA sequences cluster together (indicative of local transmission)
- V clade: Second Brazilian case has link to Switzerland rather than Milan
- F clade: new Japan cruise ship and NZ traveler (ex Iran)
- G clade: Northern Italy and central Europe

Our colleagues in Nigeria have just shared via GISAID a full genome of the newly emerging coronavirus, making it the first dataset from the African continent. It is not reflected in today's Analysis Update. Finally, after careful consideration of perspectives shared by our research community and a significant number of WHO Member States, GISAID decided to refer to the virus causing COVID-19 as hCoV-19.

We invite you to share with your colleagues

Peter

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<vincent.enouf@pasteur.fr>;

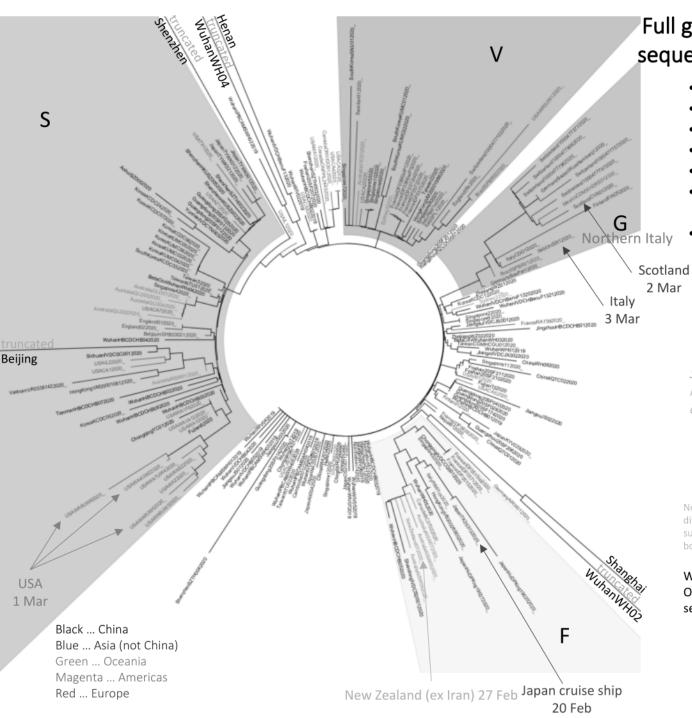
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Sent Date: 2020/03/06 14:20:40 **Delivered Date:** 2020/03/06 15:09:59

Latest update

2020-03-06 1600UTC





Full genome tree of all outbreak sequences 2020-03-06 1600UTC

- 202 full genomes shared
- New New Zealand 1
- New Japan (cruise ship) 1
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- New Italy 1
- New USA 3

Larger clades were named based on marker mutations:

S ... ORF8-L84S

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V ... NS3-G251V

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Some sequences (e.g. Beijing, Shanghai, Henan,...) have long branches due to lower quality but relative tree position reliable

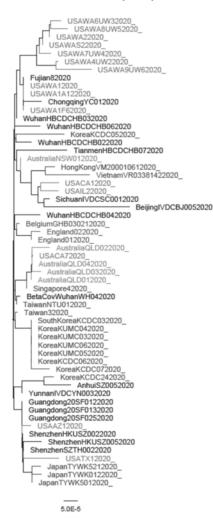
Neighbor-Joining tree with Maximum Composite Likelihood distance. Branch length in the units of the number of base substitutions per site. Uniform rates. Pairwise deletion. 500 bootstrap. MEGA X and FigTree.

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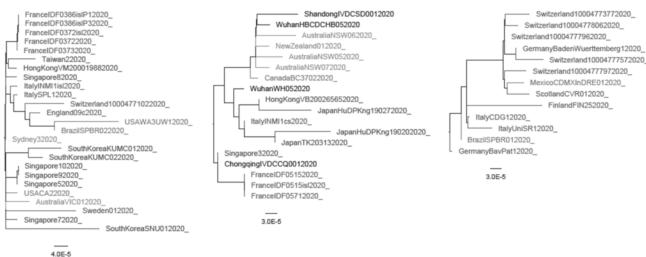


Full genome trees of major subclades 2020-03-06 1600UTC

S clade (+3)



V clade F clade (+2)



S clade: new USA-WA sequences cluster together (local transmission)

V clade: Second Brazilian case has link to Switzerland rather than Milan

F clade: new Japan cruise ship and NZ traveller (ex Iran)

G clade: Northern Italy and central Europe

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G clade (+2)

Black ... China Blue ... Asia (not China) Green ... Oceania Magenta ... Americas Red ... Europe



Full genome nucleotide alignments of all outbreak sequences 2020-03-04 UTC (202 full genomes)

Primer set names	Genomes aligned with base change	Primer set names	Genomes aligned with base change
Egene_Sarbeco (Amplicon length – 113bp) Charité	South Korea_SNU01 (EPI_ISL_411929) – T>A Jingzhou_HBCDC_HB_01 (EPI_ISL_412459) – C>T	HKU1_N (Amplicon length – 110bp) HKU	Chongqing_YC01 (EPI_ISL_408478) – C>T
RdRPgene_SARSr (Amplicon length – 100bp) Charité https://www.who.int/docs/defaul t-source/coronaviruse/protocol- v2-1.pdf	None (accepting flexibility on published ambiguous S position in reverse primer)	HKU1_ORF1b_nsp14 (Amplicon length – 132bp) HKU https://www.who.int/docs/default- source/coronaviruse/peiris-protocol-16-1 -20.pdf	Jingzhou_HBCDC_HB_01 (EPI_ISL_412459) – C>T
ChinaCDC_ORF1ab (Amplicon length – 119bp) ChinaCDC	Wuhan_WH02 (EPI_ISL_406799) – G>C	N1_USA_CDC (Amplicon length – 72bp) USA_CDC	Foshan_20SF207 (EPI_ISL_406534) – C>T Tianmen_HBCDC_HB_07 (EPI_ISL_412983) – C>T
ChinaCDC_N (Amplicon length – 99bp) ChinaCDC http://ivdc.chinacdc.cn/kyiz/2020 01/t20200121_211337.html	Wuhan_IVDC_HB_env54 (EPI_ISL_408512) - gapped Germany_Baden_Wuerttemberg (EPI_ISL_412912) - G>A, G>A, G>C	N2_USA_CDC (Amplicon length – 67bp) USA_CDC	Chongqing_YC01 (EPI_ISL_408478) - C>T
		N3_USA_CDC (Amplicon length — 72bp) USA_CDC https://www.who.int/docs/default- source/coronaviruse/uscdcrt-pcr-panel- primer-probes.pdf	Shandong_IVDC_SD_001 (EPI_ISL_408482) – T>C



Receptor binding surveillance for current 202 full genome sequences

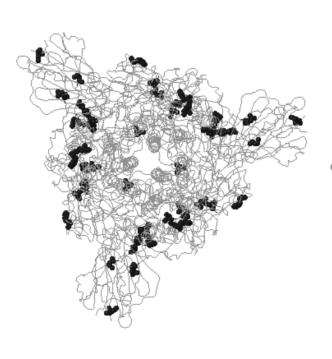
No mutation near the binding interface so far

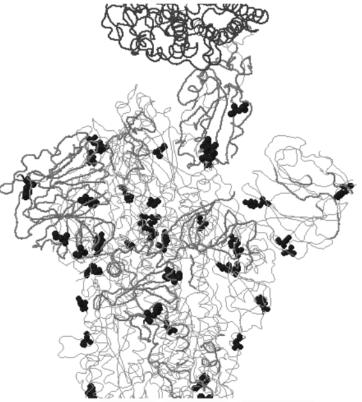
Green ... ACE2 human host receptor

Gray ... CoV spike glycoprotein

Blue ... Spike glycoprotein variation

Red ... Spike glycoprotein variation near host receptor





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Spike glycoprotein variation in structure (nearest residue if in loop region/termini)

Numbering relative to start codon 21563 in hCoV-19/Wuhan/WIV04/2019

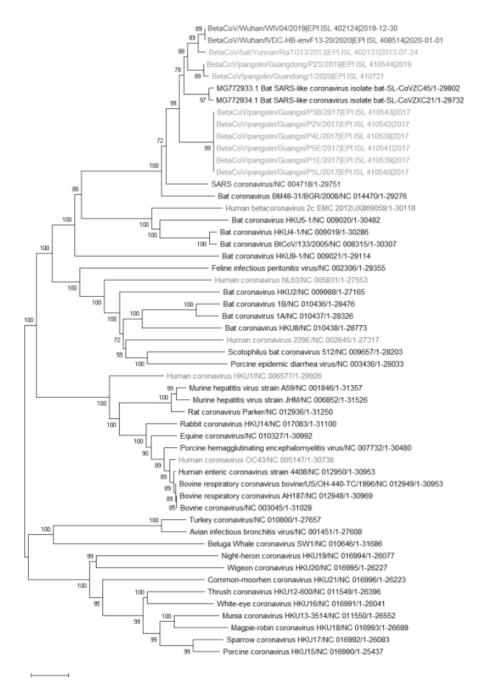
F32I H49Y S247R(249) N354D D364Y V367F D614G V1129L E1262G(1258) P1143L S221W F797C L249S L752F V615L S939F K202N H655Y (USA WA8) S254F (Germany NRW-01)



Summary

First Characterization





Full genome tree of all CoV families

- Nearest bat precursor RaTG13
- Nearest pangolin precursors from Guangdong
- Several pangolin-derived sequences part of recent family of related viruses

Genome identity to hCoV-19:

- 96% RaTG13 (nearest bat precursor)
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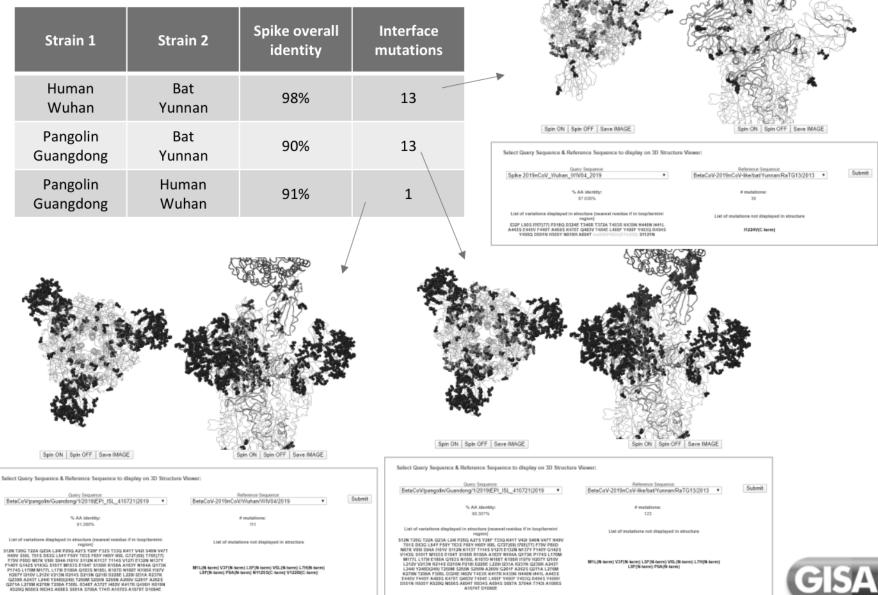
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Phylogenetic tree of Wuhan CoV full genome sequences in context of representatives of all CoV families (whole genome Neighbor Joining, Maximum Composite Likelihood, uniform rates, 500 bootstrap, MegaX)



Spike host receptor changes for nearest bat and nearest pangolin sequences



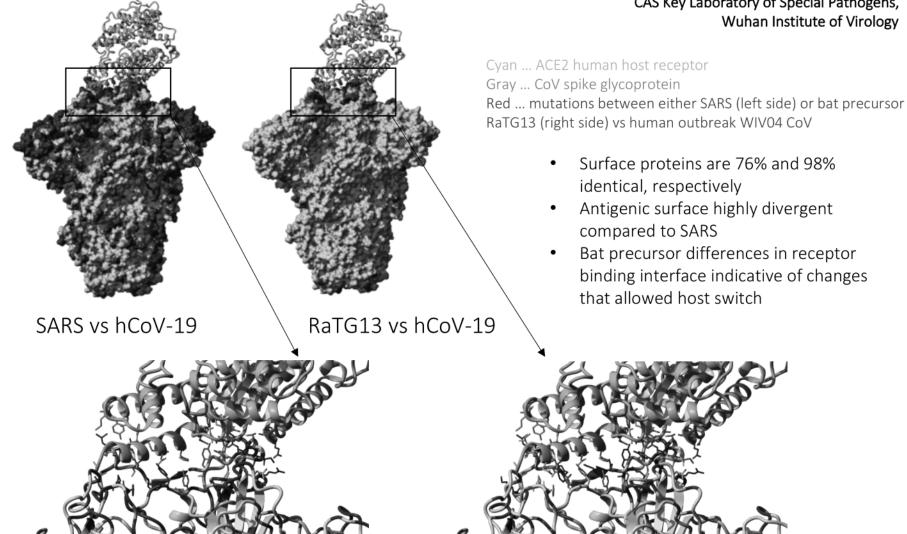


Host receptor binding site differences between SARS, bat precursor (RaTG13) and human outbreak hCoV-19

Additional Analysis for RaTG13 sequence from Zhengli Shi's lab

by BII, A*STAR Singapore

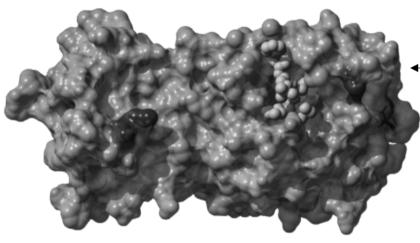
CAS Key Laboratory of Special Pathogens,



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Potential drug targets highly conserved between hCoV-19 and SARS

- Both, the main protease and polymerase which are potential drug targets are highly conserved between hCoV-19 and SARS with 96% and 97% overall identity, respectively
- Inhibitors developed against the SARS-CoV main protease or polymerase have good potential to bind similarly to hCoV-19



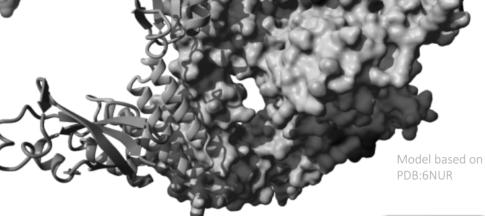
Main protease hCoV-19 vs SARS

Red ... consensus differences (surface mutations) Yellow ... substrate analogue/inhibitor

Model based on PDB:3TNT

Polymerase hCoV-19 vs SARS

nsp12 (gray=identical, red=mutated) complex with nsp7 (yellow) and nsp8 (cyan, green)



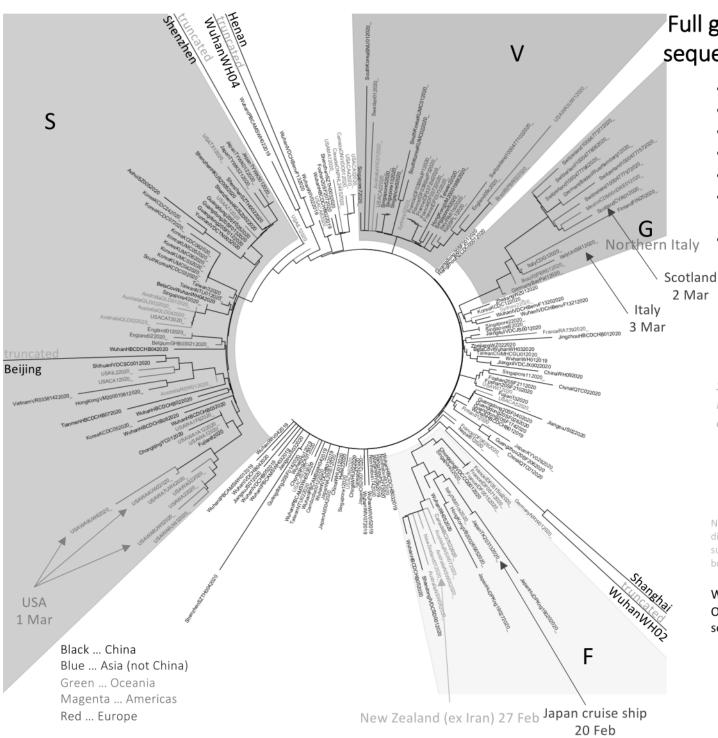
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Latest update

2020-03-06 1600UTC





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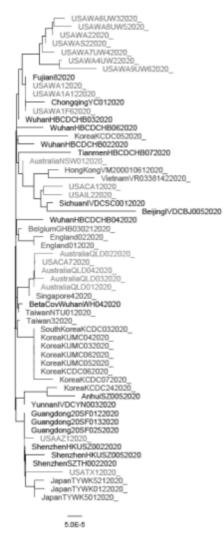
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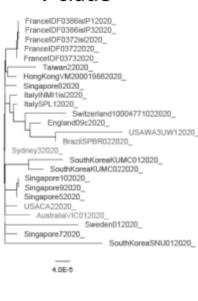


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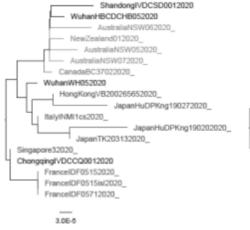
S clade (+3)



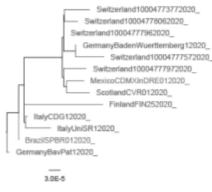
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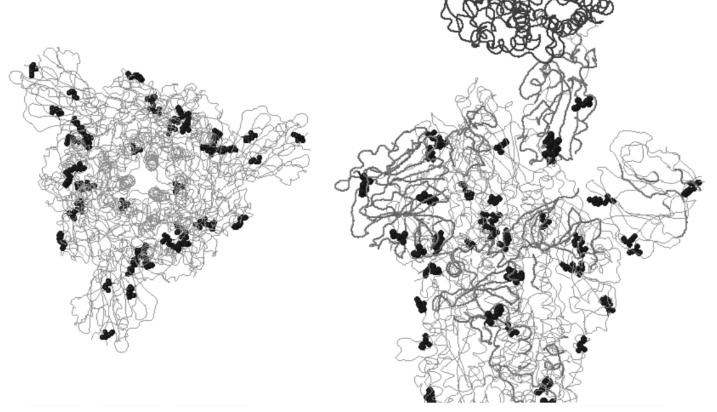
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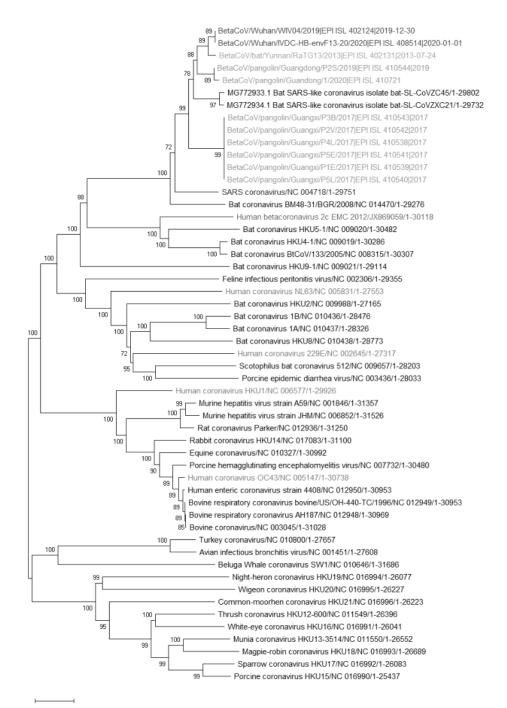
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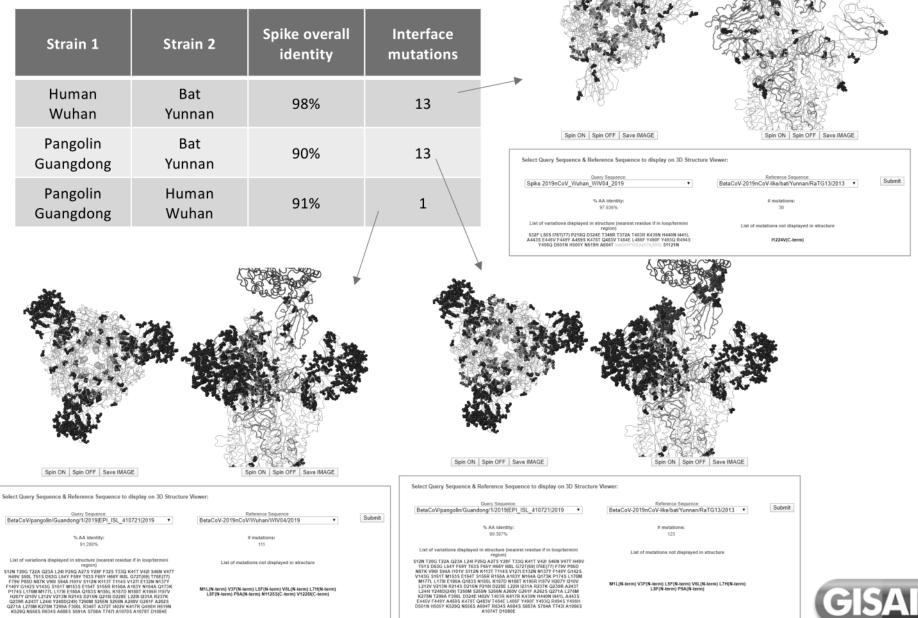
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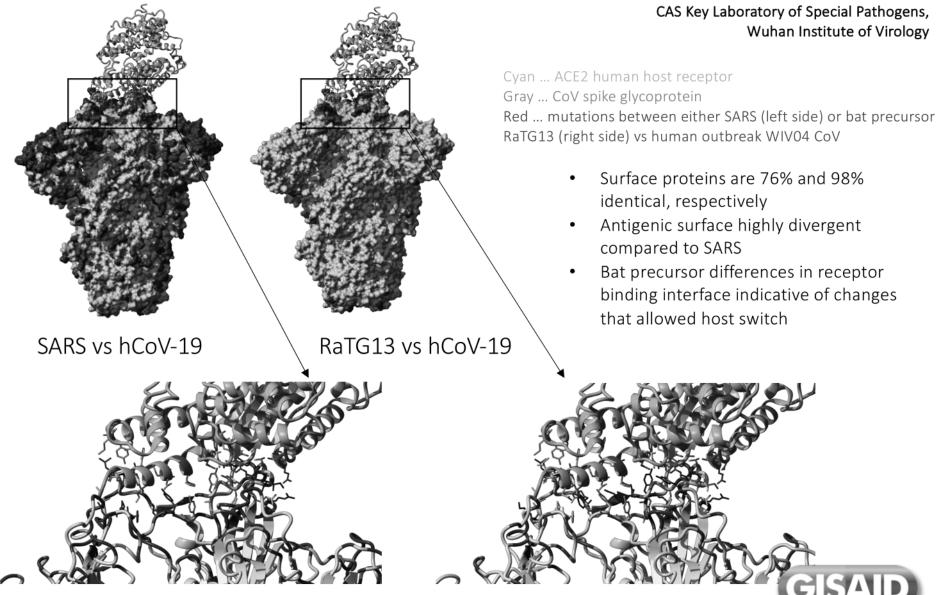
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Additional Analysis for RaTG13 sequence from Zhengli Shi's lab

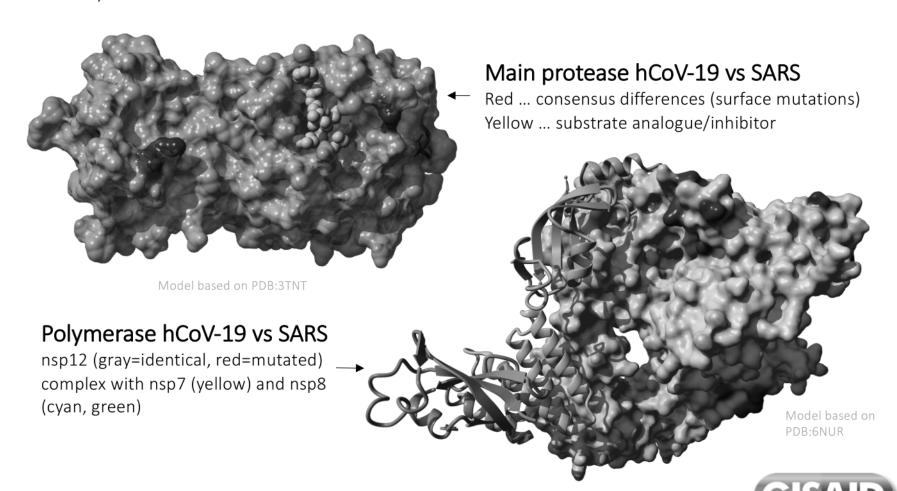


We gratefully acknowledge the Authors from Originating and Submitting laboratories of sequence data on which the analysis is based.

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Potential drug targets highly conserved between hCoV-19 and SARS

- Both, the main protease and polymerase which are potential drug targets are highly conserved between hCoV-19 and SARS with 96% and 97% overall identity, respectively
- Inhibitors developed against the SARS-CoV main protease or polymerase have good potential to bind similarly to hCoV-19



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